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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION MDL No. 2804
Case No. 17-md-2804

This document relates to: Judge Dan
Aaron Polster

The County of Cuyahoga v. Purdue Pharma, L.P., et al.
Case No. 17-OP-45005

City of Cleveland, Ohio vs. Purdue Pharma, L.P., et al.
Case No. 18-OP-45132

The County of Summit, Ohio,
et al. v. Purdue Pharma, L.P.,
et al.
Case No. 18-OP-45090

Videotaped 30(b)(6) Deposition of the
Drug Enforcement Administration
through the testimony of Stacy Harper-Avilla
Washington, D.C.

April 11, 2019
9:16 a.m.

Reported by: Bonnie L. Russo
Job No. 3282688

<p>1 Videotaped 30(b)(6) Deposition of Drug 2 Enforcement Administration through the 3 testimony of Stacy Harper-Avilla held at: 4 5 6 7 8 Arnold & Porter, LLP 9 601 Massachusetts Avenue, N.W. 10 Washington, D.C. 11 12 Pursuant to Notice, when were present on behalf 13 of the respective parties: 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>Page 2</p> <p>1 APPEARANCES (CONTINUED): 2 On behalf of Plaintiffs: 3 PAUL T FARRELL, JR , ESQ 3 (Via Teleconference) 4 GREENE KETCHUM, LLP 4 419 Eleventh Street Huntington, West Virginia 25701 5 304-525-9115 5 paul@greeneketchum.com 6 6 On behalf of Purdue Pharma, L P 7 JENNA C NEWMARK, ESQ DECHERT, LLP 8 Three Bryant Park 1095 Avenue of the Americas 9 New York, New York 10036 212-698-3500 10 jenna.newmark@dechert.com 11 On behalf of Johnson & Johnson and Janssen Pharmaceuticals, Inc 12 EMILIE K WINCKEL, ESQ OMELVENY & MYERS, LLP 13 1625 Eye Street, N W Washington, D C 20006 14 202-383-5129 ewinckel@omm.com 15 -and- AMY R LUCAS, ESQ 16 (Via Teleconference) OMELVENY & MYERS, LLP 17 1999 Avenue of the Stars, 8th Floor Los Angeles, California 90067 18 310-553-6700 alucas@omm.com 19 20 21 22 23 24 25</p>
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	Page 7	Page 9
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6			6 Please note that the microphones	
7 EXHIBITS			7 are sensitive and may pick up whispering,	
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9 Exhibit 1 Notice of Videotaped	18		9 interference. Please turn off all cell phones	
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15 February 2015			15 video-recorded deposition of the DEA, appearing	
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17 Exhibit 4 APQ Review and Approval	81		17 by counsel for defendant in the matter of In	
18 2011-2018			18 Re: National Prescription Opiate, filed in the	
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1 Exhibit 11 E-Mail Chain	164		1 firm Veritext Legal Solutions, I'm your	
2 dated 5-28-97			2 videographer. The court reporter is Bonnie	
3 P 081098-099			3 Russo from the firm Veritext Legal Solutions.	
4 Exhibit 12 E-Mail Chain	172		4 Counsel and all present in the room	
5 dated 4-4-05			5 and everyone attending remotely will now state	
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8 107 Congress			8 MR. O'CONNOR: Andrew O'Connor,	
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19 Vol 83, No 76			19 behalf of McKesson.	
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22 dated 7-12-18			22 MS. VENTURA: Catie Ventura for the	
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24 PPLPC032000404799-4807			24 MR. RUIZ: Anthony Ruiz, Zuckerman	
25 (Exhibits included with transcript)			25 Spaeder for CVS Indiana, LLC and CVS Rx	

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<p>1 Services, Inc.</p> <p>2 MS. McClURE: Shannon McClure, Reed</p> <p>3 Smith, AmerisourceBergen.</p> <p>4 MR. DAVIS: Josh Davis of Arnold &</p> <p>5 Porter for the Endo and Par defendants.</p> <p>6 MS. NEWMARK: Jenna Newmark from</p> <p>7 Dechert for the Purdue defendants.</p> <p>8 MR. LAVELLE: John Lavelle, Morgan</p> <p>9 Lewis for defendant Rite Aid of Maryland.</p> <p>10 MR. MASTERS: Brad Masters, Williams</p> <p>11 & Connolly, Cardinal Health.</p> <p>12 MR. STEPHENS: Neal Stephens, Jones</p> <p>13 Day, for Walmart.</p> <p>14 MS. WINCKEL: Emilie Winckel,</p> <p>15 O'Melveny and Myers, for the J&J defendants.</p> <p>16 MR. ELSNER: Michael Elsner from</p> <p>17 Motley Rice on behalf of the plaintiffs.</p> <p>18 MR. BENNETT: James Bennett from</p> <p>19 U.S. Attorney's Office, Cleveland, on behalf of</p> <p>20 the United States and the Department of Justice</p> <p>21 DEA.</p> <p>22 MS. SPEARS: Mariama Spears on</p> <p>23 behalf of the Drug Enforcement Administration.</p> <p>24 MR. CHANDLER: Robert Chandler,</p> <p>25 United States Department of Justice on behalf</p>	<p>1 being first duly sworn, to tell the truth, the</p> <p>2 whole truth and nothing but the truth,</p> <p>3 testified as follows:</p> <p>4</p> <p>5 THE VIDEOGRAPHER: You may proceed,</p> <p>6 Counsel.</p> <p>7</p> <p>8 EXAMINATION BY COUNSEL FOR DEFENDANTS</p> <p>9 MALLINCKRODT AND SPEC GX LLC</p> <p>10 BY MR. O'CONNOR:</p> <p>11 Q. Ms. Avilla, good morning.</p> <p>12 A. Morning.</p> <p>13 Q. I am Andrew O'Connor. I represent</p> <p>14 Mallinckrodt in this case. I will be asking</p> <p>15 you some questions on behalf of the</p> <p>16 manufacturing defendants.</p> <p>17 Would you just state your full name</p> <p>18 for the record.</p> <p>19 A. Stacy Harper-Avilla.</p> <p>20 Q. And have you ever had your</p> <p>21 deposition taken before?</p> <p>22 A. No.</p> <p>23 Q. You can cross that off your bucket</p> <p>24 list.</p> <p>25 So just a few rules of the road</p>
Page 15	Page 17
<p>1 of the United States.</p> <p>2 MR. BEISELL: Patrick Beisell, Jones</p> <p>3 Day on behalf of Walmart.</p> <p>4 MS. LUCAS: Amy Lucas, O'Melveny &</p> <p>5 Myers, on behalf of Janssen Pharmaceuticals and</p> <p>6 Johnson & Johnson.</p> <p>7 MS. MATIC: Kristina Matic on behalf</p> <p>8 of Anda.</p> <p>9 MS. BARBER: Maureen Barber from</p> <p>10 Morgan Lewis for the Teva defendants.</p> <p>11 MS. DESH: Sharon Desh on behalf of</p> <p>12 Walgreens.</p> <p>13 MR. WEISS: Eric Weiss of Cavitch</p> <p>14 Familo & Durkin on behalf of Discounted Drug</p> <p>15 Mart.</p> <p>16 MR. MARTIN: Zachary Martin, Fox</p> <p>17 Rothschild, on behalf of Prescriptions Supply.</p> <p>18 MR. HAHN: William Hahn on behalf of</p> <p>19 H.D. Smith from Barnes and Thornburg.</p> <p>20 MR. MONTMINY: Brandon Montminy on</p> <p>21 behalf of the Henry Schein defendants.</p> <p>22 THE VIDEOGRAPHER: Will the court</p> <p>23 reporter please swear in the witness.</p> <p>24</p> <p>25 STACY HARPER-AVILLA,</p>	<p>1 before we get going. First, just to make the</p> <p>2 court reporter's life a little easier, we're</p> <p>3 going to try to talk one at a time. I will ask</p> <p>4 my question and I would just ask that you wait</p> <p>5 until I finish before you start and I will do</p> <p>6 the same as you are answering. Rather than</p> <p>7 shaking your head or nodding, also make sure to</p> <p>8 give verbal answers.</p> <p>9 Does that make sense?</p> <p>10 A. Yes.</p> <p>11 Q. And if I ask a question and I am not</p> <p>12 clear or you don't understand, just let me</p> <p>13 know, and if you don't let me know, I'm just</p> <p>14 going to assume that you understood the</p> <p>15 question as I asked it.</p> <p>16 Does that make sense?</p> <p>17 A. Yes.</p> <p>18 Q. Is there anything that would prevent</p> <p>19 you from testifying completely and truthfully</p> <p>20 today?</p> <p>21 A. No.</p> <p>22 Q. And you understand that today you</p> <p>23 are providing testimony on behalf of the DEA?</p> <p>24 A. Yes.</p> <p>25 MR. O'CONNOR: I'm going to mark</p>

5 (Pages 14 - 17)

<p style="text-align: right;">Page 18</p> <p>1 Exhibit 1. 2 (Deposition Exhibit 1 was marked for 3 identification.) 4 BY MR. O'CONNOR: 5 Q. This is a notice of deposition. 6 Have you ever seen this document 7 before? 8 A. Yes. 9 Q. And I'm going to ask you to turn to 10 Exhibit B, which is the letter from the U.S. 11 Department of Justice. 12 Have you ever seen this document 13 before? 14 A. Yes. 15 Q. Okay. And do you understand it to 16 be the letter authorizing testimony on certain 17 subjects on behalf of the DEA? 18 A. Yes. 19 Q. Let's go ahead and turn to Page 6 20 and I direct your attention to Topic 13. 21 It says: "Topic 13. Your practices 22 and procedures related to the establishment of 23 opioid procurement quotas and opioid production 24 quotas for prescription opioids." 25 Are you authorized by the DEA to</p>	<p style="text-align: right;">Page 20</p> <p>1 requests and the disposition of quota requests 2 and the relationship between quota, suspicious 3 orders, diversion and lawful medical, 4 scientific or industrial channels or use."</p> <p>5 Did I read that correctly?</p> <p>6 A. Yes.</p> <p>7 Q. And are you authorized by DEA to 8 provide testimony on that topic today?</p> <p>9 A. Yes.</p> <p>10 Q. So when I ask a question, unless I 11 specifically indicate that I am asking for your 12 personal opinion, I am going to be asking for 13 the DEA's answer to that question.</p> <p>14 Does that make sense?</p> <p>15 A. Yes.</p> <p>16 MR. CHANDLER: Andrew, so that I 17 understand, is your initial questioning going 18 to relate to plaintiff's Topic No. 3 as well, 19 or is that only going to be sort of 20 reexamination following the plaintiff's 21 examination?</p> <p>22 MR. O'CONNOR: There will probably 23 be some overlap so it could pertain to any one 24 of those three topics.</p> <p>25 MR. CHANDLER: Okay. And that is</p>
<p style="text-align: right;">Page 19</p> <p>1 testify regarding that topic today? 2 A. Yes. 3 Q. And I now direct your attention to: 4 "Topic 14, the basis for opioid procurement 5 quotas and opioid production quotas of 6 prescriptions from 1995 to 2018." 7 Are you authorized by the DEA to 8 provide testimony regarding that topic today? 9 A. Yes. 10 Q. Okay. 11 MR. CHANDLER: I do want to note for 12 the record that Ms. Avilla's authorization 13 extends insofar as the qualifications that are 14 also included in this letter. 15 MR. O'CONNOR: Understood. 16 BY MR. O'CONNOR: 17 Q. If you could turn to Page 9 of that 18 same document. 19 And look at Topic 3, which reads: 20 "DEA's establishment of quotas for the 21 production of opioids in the United States 22 including aggregate production quotas, 23 individual quotas and procurement quotas, the 24 disclosure of quota to registrants, 25 communications with registrants regarding quota</p>	<p style="text-align: right;">Page 21</p> <p>1 understood between you and the plaintiffs? I 2 am trying to understand how this is going to 3 flow back and forth between the two notices.</p> <p>4 MR. O'CONNOR: I think we are 5 entitled to question on any one of the topics 6 for which she is authorized, and so we will be 7 proceeding on that basis.</p> <p>8 MR. CHANDLER: Okay.</p> <p>9 MR. ELSNER: This is Michael 10 Elsner. I'm going to object. You are entitled 11 to ask questions on your topics but not on our 12 topics.</p> <p>13 MR. O'CONNOR: I think we would 14 disagree about that, but I think -- let's see 15 how it goes and if we need to resolve it, we 16 can do so offline.</p> <p>17 BY MR. O'CONNOR:</p> <p>18 Q. Ms. Avilla, what is your current 19 role at DEA?</p> <p>20 A. I'm the section chief of United 21 Nations Reporting and Quota Section.</p> <p>22 Q. And what do your responsibilities in 23 that role include?</p> <p>24 A. The responsibilities are to manage 25 the quotas for controlled substances in</p>

<p style="text-align: right;">Page 22</p> <p>1 Schedules I and II, report back to the UN on 2 the U.S. -- usage consumption of those 3 substances as well as for setting the 4 assessments and estimates for items in 5 Schedules III through V, controlled substances 6 in III through V.</p> <p>7 Q. How long have you been in that 8 position?</p> <p>9 A. Since July of last year.</p> <p>10 Q. Before that, did you hold any 11 position at DEA?</p> <p>12 A. Yes, I did.</p> <p>13 Q. What was that?</p> <p>14 A. I was the unit chief of the same 15 section.</p> <p>16 Q. You were working with quotas in that 17 role as well?</p> <p>18 A. Yes.</p> <p>19 Q. What was your position at DEA, if 20 any, before that time?</p> <p>21 A. I don't understand the question.</p> <p>22 Q. Did you have a job at DEA before 23 that role as unit chief?</p> <p>24 A. Yes.</p> <p>25 Q. What was that?</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. Okay. Do you remember what sorts of 2 documents?</p> <p>3 A. No.</p> <p>4 Q. Were they e-mails?</p> <p>5 A. There were a lot of documents. I 6 don't know. I don't remember precisely what 7 now.</p> <p>8 Q. Okay. Without getting into any 9 communications you had with lawyers, what are 10 the names of the people that you spoke with to 11 prepare for this deposition?</p> <p>12 A. I spoke with Dr. Chris Sannerud and 13 Mr. Joe Rannazzisi.</p> <p>14 Q. Who is Ms. Sannerud?</p> <p>15 A. Dr. Sannerud was the section chief 16 before me.</p> <p>17 Q. Okay. And is Dr. Sannerud still 18 employed by DEA?</p> <p>19 A. No.</p> <p>20 Q. When did she leave the DEA?</p> <p>21 A. July of last year.</p> <p>22 Q. And who is Mr. Rannazzisi?</p> <p>23 A. He is a retired DEA special agent.</p> <p>24 Q. During your discussions -- or your 25 discussions with Dr. Sannerud, was there anyone</p>
<p style="text-align: right;">Page 23</p> <p>1 A. Drug science specialist.</p> <p>2 Q. Okay. When you were a drug science 3 specialist, did you have any involvement in 4 quota issues?</p> <p>5 A. Yes.</p> <p>6 Q. Was that role your first at DEA?</p> <p>7 A. Yes.</p> <p>8 Q. And when did you start in that role?</p> <p>9 A. 2008.</p> <p>10 Q. So am I correct that you joined the 11 Drug Enforcement Administration in 2008?</p> <p>12 A. Correct.</p> <p>13 Q. Okay. And since that time, your 14 work has included work on quota-related 15 matters?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. Did you prepare for this 18 deposition?</p> <p>19 A. Yes.</p> <p>20 Q. How did you prepare?</p> <p>21 A. By reviewing the statute, the regs.</p> <p>22 Q. Did you review anything else?</p> <p>23 A. Yes. Yes.</p> <p>24 Q. What else did you review?</p> <p>25 A. Documents for clarification.</p>	<p style="text-align: right;">Page 25</p> <p>1 else in the room or on the phone?</p> <p>2 A. I don't understand the question.</p> <p>3 Q. When you had discussions to prepare 4 for this deposition with Dr. Sannerud --</p> <p>5 A. Yes.</p> <p>6 Q. -- was there anyone else in the room 7 with you?</p> <p>8 A. The lawyers.</p> <p>9 Q. The lawyers. Okay. And when you 10 say, "the lawyers," who do you mean?</p> <p>11 A. The DEA lawyers, DEA attorneys.</p> <p>12 Q. Okay. Were there any attorneys 13 besides attorneys working for DEA?</p> <p>14 A. The ones working for DOJ.</p> <p>15 Q. Okay. And besides lawyers working 16 for DOJ, were there any other lawyers?</p> <p>17 A. Not that I know of. Not that I 18 remember.</p> <p>19 Q. And during your conversations with 20 Mr. Rannazzisi, who was in the room with you or 21 on the phone?</p> <p>22 A. In the room where the DOJ and DEA 23 attorneys.</p> <p>24 Q. Okay. And besides those attorneys, 25 was there anyone else on the phone or in the</p>

<p>1 room?</p> <p>2 A. In the room, no.</p> <p>3 Q. Were there others on the phone?</p> <p>4 A. I don't know.</p> <p>5 Q. Do you know if anyone was on the</p> <p>6 phone?</p> <p>7 A. Mr. Rannazzisi was on the phone.</p> <p>8 Q. Okay. And regarding the documents</p> <p>9 that you reviewed in preparation for today, did</p> <p>10 you choose those documents yourself?</p> <p>11 A. Yes.</p> <p>12 Q. How did you choose those documents?</p> <p>13 A. They were areas that encompassed</p> <p>14 what was required for the UN reporting and</p> <p>15 quota section.</p> <p>16 Q. Okay. What sort of documents are we</p> <p>17 talking about?</p> <p>18 MR. CHANDLER: I'm going to step in</p> <p>19 here.</p> <p>20 To the extent that your answer</p> <p>21 requires you to disclose any of our</p> <p>22 communications or communications with any of</p> <p>23 the government lawyers, I will instruct you not</p> <p>24 to answer.</p> <p>25 If you can answer subject to that,</p>	<p>Page 26</p> <p>1 A. I don't know. I didn't quantify it.</p> <p>2 Q. Okay. Roughly how many meetings did</p> <p>3 you have with DOJ or DEA attorneys about today?</p> <p>4 A. I don't have an exact number.</p> <p>5 Q. How about an estimate?</p> <p>6 A. Less than ten.</p> <p>7 Q. Less than ten. Okay. About how</p> <p>8 long were those meetings?</p> <p>9 A. They were usually several hours.</p> <p>10 Q. Okay. When you say, "less than</p> <p>11 ten," do you think there was more than five?</p> <p>12 A. Probably.</p> <p>13 Q. Okay. All right. So I want to turn</p> <p>14 back to your responsibilities as unit chief of</p> <p>15 the UN reporting and quota section.</p> <p>16 In that role, what responsibility</p> <p>17 did you have with respect to establishing</p> <p>18 quotas for Schedule I and II controlled</p> <p>19 substances?</p> <p>20 A. To review the incoming applications,</p> <p>21 to review documentation, review and assess</p> <p>22 whether it was scientifically accurate.</p> <p>23 Q. Okay. Who did you report to when</p> <p>24 you were unit chief?</p> <p>25 A. Dr. Chris Sannerud.</p>
<p>1 that caveat, you can answer.</p> <p>2 BY MR. O'CONNOR:</p> <p>3 Q. So without getting into the</p> <p>4 communications with your lawyers, what sorts of</p> <p>5 documents did you select?</p> <p>6 A. I can't answer.</p> <p>7 Q. I'm sorry?</p> <p>8 A. I can't answer.</p> <p>9 Q. And why can't you answer?</p> <p>10 A. A lot of that is communication</p> <p>11 shared with the attorneys.</p> <p>12 Q. Okay. In preparing for today's</p> <p>13 deposition, did you speak with anyone else at</p> <p>14 DEA other than the lawyers, Dr. Sannerud and</p> <p>15 Mr. Rannazzisi?</p> <p>16 A. No.</p> <p>17 Q. Did you speak with anyone else who</p> <p>18 has testified previously in this matter?</p> <p>19 A. Not to my knowledge.</p> <p>20 Q. Did you speak with anyone outside</p> <p>21 DEA in preparing for this deposition, other</p> <p>22 than those we've already discussed?</p> <p>23 A. No.</p> <p>24 Q. Okay. About how much time did you</p> <p>25 spend preparing for today?</p>	<p>Page 27</p> <p>1 Q. Okay. And did there come a time</p> <p>2 where you were promoted to section chief?</p> <p>3 A. Yes.</p> <p>4 Q. And at that time, who did you report</p> <p>5 to?</p> <p>6 A. Susan Gibson.</p> <p>7 Q. And what is Ms. Gibson's position?</p> <p>8 A. I'm not sure.</p> <p>9 Q. Okay.</p> <p>10 A. I'm not sure. She is in New Jersey</p> <p>11 at this point.</p> <p>12 Q. Okay. Is she your current</p> <p>13 supervisor?</p> <p>14 A. No.</p> <p>15 Q. Who is your current supervisor?</p> <p>16 A. Raymond Brown, Special Agent Raymond</p> <p>17 Brown.</p> <p>18 Q. And what is his position at DEA?</p> <p>19 A. Deputy assistant administrator.</p> <p>20 Q. In your role as unit chief and now</p> <p>21 section chief, did you come to have an</p> <p>22 understanding of the DEA's practices and</p> <p>23 procedures related to the establishment of</p> <p>24 quotas?</p> <p>25 A. Yes.</p>

<p>1 Q. And did that include -- did your 2 understanding include the procedures and 3 practices specifically related to aggregate 4 production quota?</p> <p>5 A. Yes.</p> <p>6 Q. And does it also include practices 7 and procedures related to the procurement quota 8 process?</p> <p>9 A. Yes.</p> <p>10 Q. Does it also include individual 11 manufacturing quotas?</p> <p>12 A. Yes.</p> <p>13 Q. In those positions, did you also 14 gain an understanding of the basis or the 15 reasons why those quotas were set where they 16 were?</p> <p>17 A. Yes.</p> <p>18 Q. And through your work, did you also 19 get an understanding of the reasons the DEA had 20 for increasing the quota from year to year with 21 respect to certain substances?</p> <p>22 MR. CHANDLER: Objection. Vague. 23 BY MR. O'CONNOR: 24 Q. You can answer the question. 25 A. Each year the quota is built</p>	<p style="text-align: right;">Page 30</p> <p>1 MR. CHANDLER: Objection. Vague. 2 THE WITNESS: From the manufacturers 3 to the pharmacy, yes, they should be. 4 BY MR. O'CONNOR: 5 Q. Okay. So manufacturers, 6 distributors, pharmacies are all DEA 7 registrants, correct? 8 A. If they handle controlled 9 substances, yes. 10 Q. I want to turn to manufacturers for 11 a minute. 12 In order to manufacture controlled 13 substances with approval from DEA, what steps 14 does a manufacturer need to take? 15 MR. CHANDLER: Objection. Vague. 16 Scope. 17 BY MR. O'CONNOR: 18 Q. You can answer. 19 A. I don't understand the question. 20 Q. Okay. Do manufacturers need to 21 request a quota grant before they can produce 22 controlled substances? 23 A. Yes. 24 Q. Are manufacturers permitted to 25 manufacture any more of a controlled substance</p>
<p>1 individually. It's not a year-to-year 2 situation.</p> <p>3 Q. Okay. And in any given year during 4 your time at DEA, you understood the reasons 5 the quota was set at the level that it was set 6 at; is that fair?</p> <p>7 A. Yes.</p> <p>8 MR. CHANDLER: Objection. Vague. 9 BY MR. O'CONNOR: 10 Q. Are you familiar with the term 11 "closed system of distribution?"</p> <p>12 A. Yes.</p> <p>13 Q. What do you understand that term to 14 mean?</p> <p>15 MR. CHANDLER: Objection. Scope. 16 You can answer.</p> <p>17 THE WITNESS: It means that the 18 controlled substance is monitored within a 19 system set up by the Controlled Substances Act 20 from the manufacturer down to the pharmacy 21 level in the ultimate locations.</p> <p>22 BY MR. O'CONNOR: 23 Q. And the players at those various 24 levels that you just mentioned are all DEA 25 registrants, correct?</p>	<p style="text-align: right;">Page 31</p> <p>1 than DEA permits through its quota process? 2 A. No. 3 Q. Is it fair to say that DEA has the 4 ability to decline to provide any given 5 manufacturer with a quota grant? 6 A. I don't understand the question. 7 Q. Is DEA required to grant 8 manufacturers quota? 9 MR. CHANDLER: Objection. Vague. 10 THE WITNESS: I don't understand the 11 question. 12 BY MR. O'CONNOR: 13 Q. So in your role, are you involved 14 with the consideration and approval of quota 15 requests? 16 A. Yes. 17 Q. Are you required to approve every 18 request? 19 A. No. 20 Q. That's because the DEA does not -- 21 is not required to approve every request, 22 correct? 23 A. Correct. 24 Q. Are you familiar with any statute 25 that sets forth DEA's authority to grant quota?</p>

<p style="text-align: right;">Page 34</p> <p>1 A. I don't understand the question. 2 Q. Is there any statute that grants the 3 Drug Enforcement Administration the authority 4 to set quota for controlled substances? 5 A. Yes. 6 Q. Are you familiar with that statute? 7 A. Yes. 8 Q. Are there any regulations that DEA 9 has promulgated that set forth the process for 10 setting the quota for controlled substances? 11 A. Yes. 12 Q. And in your role as unit chief and 13 then section chief, was one of your 14 responsibilities to apply the processes that 15 were described by statute and regulation in 16 determining the amount of quota? 17 MR. CHANDLER: Objection. Vague. 18 Compound. 19 BY MR. O'CONNOR: 20 Q. You can answer. 21 A. Yes. 22 Q. Are you familiar with the term 23 "aggregate production quota?" 24 A. Yes. 25 Q. What does that term mean?</p>	<p style="text-align: right;">Page 36</p> <p>1 with quota, what is the nature of the FDA's 2 involvement? 3 MR. ELSNER: Objection. 4 MR. CHANDLER: I will object. Vague 5 as to time. 6 BY MR. O'CONNOR: 7 Q. Do you recall any times in which FDA 8 was involved in discussions regarding quota? 9 A. I don't understand the question. 10 Q. You mentioned that at times, you 11 consulted with FDA in connection with quota, 12 correct? 13 A. Yes. 14 Q. When did that happen? 15 MR. CHANDLER: Objection. Vague. 16 You can answer. 17 THE WITNESS: By statute, by FDA 18 statute, they are required to consult with us. 19 We are required to have a dialogue however it 20 takes place. 21 BY MR. O'CONNOR: 22 Q. And did DEA comply with its 23 obligation to have discussions with FDA? 24 A. Yes. 25 Q. Did DEA consult with FDA in</p>
<p style="text-align: right;">Page 35</p> <p>1 A. In summary, it is the maximum amount 2 that the United States actually needs for its 3 domestic needs, for legitimate, medical, 4 scientific, research needs, exportation needs 5 and inventory allowances. 6 Q. Okay. Does DEA determine what that 7 number is on an annual basis? 8 MR. CHANDLER: Objection. Vague. 9 You can answer. 10 THE WITNESS: I don't understand the 11 question. 12 BY MR. O'CONNOR: 13 Q. Is DEA responsible for determining 14 the aggregate production quota? 15 A. DEA is the agency that publishes it, 16 but we work in concert with other agencies. 17 Q. Okay. What other agencies do you 18 work with? 19 A. FDA. 20 Q. Any other agencies? 21 A. When necessary, yes. 22 Q. What would those other agencies be? 23 A. Those within the bounds of DOJ and 24 HHS. 25 Q. When you work with FDA in connection</p>	<p style="text-align: right;">Page 37</p> <p>1 connection with the aggregate production quota 2 every year? 3 A. I can't guarantee every year, but 4 yes, as far as I know, I have seen 5 documentation for almost every year. 6 Q. Okay. What form did that 7 documentation take? 8 A. A letter. 9 Q. Okay. Would there be discussions 10 between the FDA and DEA prior to FDA sending 11 that letter? 12 A. Not that I'm aware of. There may 13 be, but I don't know of any that were 14 documented. 15 Q. Okay. Besides yourself, how many 16 others at DEA work on quota-related issues? 17 MR. ELSNER: Objection. Timing. 18 BY MR. O'CONNOR: 19 Q. Today -- strike that. 20 Today, how many people at DEA work 21 on quota-related issues? 22 MR. CHANDLER: Objection. Vague. 23 THE WITNESS: I'm not sure I 24 understand the question. 25 BY MR. O'CONNOR:</p>

<p style="text-align: right;">Page 38</p> <p>1 Q. You are not the only person at DEA 2 that works on quota, correct? 3 A. Correct. 4 Q. Okay. Roughly how many other people 5 are involved in the process of setting 6 aggregate production quotas? 7 A. There are several people involved in 8 several different sections for setting an 9 aggregate production quota and I don't know who 10 all of the people are, just the sections that 11 they go through. 12 Q. Okay. When you were unit chief, how 13 many people approximately worked in your 14 section -- in your unit. Sorry. 15 A. It varied over the years. 16 Q. So when you first started as unit 17 chief, approximately how many people worked in 18 your unit? 19 A. Four or five people. 20 Q. Okay. Were they full-time 21 employees? 22 A. Yes. 23 Q. Did that number change over time? 24 A. Yes. 25 Q. When did it change?</p>	<p style="text-align: right;">Page 40</p> <p>1 BY MR. O'CONNOR: 2 Q. Safe to say that as the unit chief, 3 if you felt they were not able to discharge 4 their duties, you would have done something 5 about that, right? 6 MR. ELSNER: Objection. 7 THE WITNESS: I would have provided 8 extra training, yes. 9 BY MR. O'CONNOR: 10 Q. You mentioned that at times, DEA 11 communicated with HHS in connection with the 12 quota. 13 On what subjects would DEA 14 communicate with HHS when it came to quota 15 issues? 16 A. So I mentioned that DEA communicated 17 with FDA within HHS on quota issues. 18 Q. Were there any other agencies or 19 departments within HHS that DEA communicated 20 with on quota issues? 21 MR. ELSNER: Objection. 22 BY MR. O'CONNOR: 23 Q. You can answer the question. 24 A. There would have been SAMSHA at the 25 time probably.</p>
<p style="text-align: right;">Page 39</p> <p>1 A. I don't recall. It just -- it 2 changed when people made clearance. 3 Q. Did the group get bigger or smaller? 4 A. Bigger. 5 Q. Okay. Roughly how big did it get? 6 A. I don't understand the question. 7 Q. When the group was at its biggest, 8 how many people were in it? 9 A. Ten, 12 people. 10 Q. Were all of those individuals 11 involved in the process of determining quota? 12 A. Yes. 13 Q. Okay. Did those individuals who 14 were involved in the quota process receive any 15 training regarding quota? 16 MR. CHANDLER: Objection. Vague. 17 THE WITNESS: I'm not sure I 18 understand the question. 19 BY MR. O'CONNOR: 20 Q. Did the people who worked on quota 21 have the training they needed in your view to 22 do their job? 23 MR. CHANDLER: Objection. Vague. 24 Scope. 25 THE WITNESS: Yes.</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. What is SAMSHA? 2 A. I don't remember the full name. 3 Q. Fair enough. Do you know generally 4 speaking what SAMSHA does? 5 A. Substance abuse and mental health. 6 Q. Okay. Between 1995 and 2018, was 7 DEA -- or did DEA consult with SAMSHA on a 8 regular basis in connection with quota? 9 MR. CHANDLER: Objection. Vague. 10 THE WITNESS: I don't understand the 11 question. 12 BY MR. O'CONNOR: 13 Q. Did DEA communicate with SAMSHA more 14 than once? 15 A. Yes. 16 Q. Did DEA communicate with SAMSHA on a 17 yearly basis regarding quota? 18 A. Probably, not directly. 19 Q. If not directly, how would DEA 20 communicate with SAMSHA? 21 A. SAMSHA's concerns were usually 22 placed in FDA's letter to DEA. 23 Q. Okay. Would DEA consider the FDA's 24 input when determining the aggregate production 25 quota?</p>

<p style="text-align: right;">Page 42</p> <p>1 A. Yes.</p> <p>2 Q. And would DEA consider SAMSHA's</p> <p>3 input when determining the aggregate production</p> <p>4 quota?</p> <p>5 A. Yes, when it was there.</p> <p>6 Q. Okay. What else would DEA consider</p> <p>7 when determining the aggregate production</p> <p>8 quota?</p> <p>9 A. DEA would also consider the</p> <p>10 manufacturer's quota application, changes in</p> <p>11 marketplace, manufacturer's changes to their</p> <p>12 processes, export requirements, inventory</p> <p>13 allowances that needed to be done, new</p> <p>14 indication, removal of indications, changes in</p> <p>15 FDA approval. Or changes in -- yeah, changes</p> <p>16 in FDA approval.</p> <p>17 Q. Okay. Between 1995 and 2018, did</p> <p>18 the DEA consider all those factors when setting</p> <p>19 quota?</p> <p>20 A. Yes, that's part of the whole</p> <p>21 statement.</p> <p>22 Q. So if someone claimed that DEA made</p> <p>23 a decision about quota based on only one of</p> <p>24 those factors, would you agree with them?</p> <p>25 MR. CHANDLER: Objection. Vague.</p>	<p style="text-align: right;">Page 44</p> <p>1 aggregate production quota for each of those</p> <p>2 individual classes, does it consider all those</p> <p>3 factors that you mentioned a moment ago?</p> <p>4 A. Yes.</p> <p>5 Q. Let's talk for a minute about</p> <p>6 manufacturing quotas.</p> <p>7 What do you understand the term</p> <p>8 "manufacturing quota" to mean?</p> <p>9 A. It is the quota granted to a bulk</p> <p>10 manufacturer who synthesizes or extracts</p> <p>11 aggregate -- active pharmaceutical ingredients</p> <p>12 from either a noncontrolled substance or a</p> <p>13 plant or from one controlled substance into</p> <p>14 another.</p> <p>15 Q. Okay. How does DEA determine what</p> <p>16 manufacturing quotas to grant?</p> <p>17 MR. CHANDLER: Objection. Vague.</p> <p>18 MR. ELSNER: Objection.</p> <p>19 BY MR. O'CONNOR:</p> <p>20 Q. You can answer.</p> <p>21 A. For the manufacturing quota, it is</p> <p>22 built on their customers and their</p> <p>23 manufacturing processes, as well as inventory</p> <p>24 allowances and any other FDA notifications that</p> <p>25 we have received.</p>
<p style="text-align: right;">Page 43</p> <p>1 Scope.</p> <p>2 MR. ELSNER: Objection.</p> <p>3 THE WITNESS: I would not agree with</p> <p>4 them.</p> <p>5 BY MR. O'CONNOR:</p> <p>6 Q. DEA sets aggregate production quotas</p> <p>7 for each individual class of controlled</p> <p>8 substances; is that fair?</p> <p>9 A. DEA sets quota for each class of</p> <p>10 Schedule I or Schedule II controlled substance</p> <p>11 Q. Fair enough. And what do you mean</p> <p>12 when you say, "class of controlled substance?"</p> <p>13 A. A class is the basic substance.</p> <p>14 Q. Would that include things like</p> <p>15 oxycodone?</p> <p>16 A. Yes.</p> <p>17 Q. Hydrocodone?</p> <p>18 A. Yes.</p> <p>19 Q. Hydromorphone?</p> <p>20 A. Yes.</p> <p>21 Q. Morphine?</p> <p>22 A. Yes.</p> <p>23 Q. Oxymorphone?</p> <p>24 A. Yes.</p> <p>25 Q. And when DEA is setting the</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. Okay. And couldn't the -- can any</p> <p>2 given manufacturer make more of a particular</p> <p>3 class of controlled substances than the DEA</p> <p>4 permits?</p> <p>5 MR. ELSNER: Objection.</p> <p>6 THE WITNESS: I think there is a</p> <p>7 difference between "can" and "should."</p> <p>8 BY MR. O'CONNOR:</p> <p>9 Q. Fair enough. Would it be legal for</p> <p>10 a manufacturer to produce more of a controlled</p> <p>11 substance than permitted by its DEA quota?</p> <p>12 A. Not to my knowledge, it's not legal.</p> <p>13 Q. Okay. And are you aware of any</p> <p>14 circumstances in which a manufacturer did make</p> <p>15 more than what it was permitted?</p> <p>16 A. It has occurred on occasion and DEA</p> <p>17 has taken action with the manufacturer.</p> <p>18 Q. Okay. Is it fair to say that DEA</p> <p>19 takes steps to ensure that manufacturers don't</p> <p>20 make more than what they are permitted to under</p> <p>21 their DEA quota?</p> <p>22 MR. CHANDLER: Objection. Scope.</p> <p>23 THE WITNESS: Can you repeat the</p> <p>24 question.</p> <p>25 BY MR. O'CONNOR:</p>

12 (Pages 42 - 45)

<p style="text-align: right;">Page 46</p> <p>1 Q. Sure. Is it fair to say that DEA 2 takes steps to ensure that manufacturers don't 3 make more than what they are permitted to under 4 their DEA quota?</p> <p>5 MR. CHANDLER: Same objection.</p> <p>6 THE WITNESS: When DEA has notice of 7 it, yes.</p> <p>8 BY MR. O'CONNOR:</p> <p>9 Q. Are you familiar with the term 10 "procurement quota?"</p> <p>11 A. Yes.</p> <p>12 Q. What is procurement quota?</p> <p>13 A. Procurement quota is the maximum 14 amount of quota -- maximum amount of material a 15 manufacturer can obtain.</p> <p>16 Q. Is the amount of -- strike that.</p> <p>17 DEA sets the procurement quota for 18 each manufacturer, correct?</p> <p>19 A. Of a Schedule I or II controlled 20 substance, yes.</p> <p>21 Q. How does DEA determine how to set 22 the production quota for any given 23 manufacturer? I'm sorry, strike that.</p> <p>24 How does DEA determine the 25 procurement quota for any given registrant?</p>	<p style="text-align: right;">Page 48</p> <p>1 A. Correct.</p> <p>2 Q. So, for example, oxycodone would 3 have -- strike that.</p> <p>4 So, for example, there would be a 5 specific procurement quota grant to a 6 manufacturer for oxycodone?</p> <p>7 A. Correct.</p> <p>8 Q. That would be separate from any 9 procurement grant for Hydrocodone?</p> <p>10 A. Correct.</p> <p>11 Q. And DEA would make an assessment 12 about the appropriate procurement quota for 13 each molecule separately?</p> <p>14 A. Yes.</p> <p>15 Q. And a manufacturer would not be 16 allowed to procure more of that molecule than 17 the DEA permitted, correct?</p> <p>18 A. Can I have the question repeated.</p> <p>19 Q. Sure. And a manufacturer would not 20 be allowed to procure more of that molecule 21 than the DEA permitted, correct?</p> <p>22 A. I think there is a difference 23 between would or ability to and should they, 24 when the processes work, no they cannot do 25 that. If the process does not work, then they</p>
<p style="text-align: right;">Page 47</p> <p>1 A. It would be based on their business 2 activity which is individual to the 3 manufacturer.</p> <p>4 Q. Okay. When you say, "business 5 activity," what do you mean?</p> <p>6 A. It is based on the rationale that 7 they provide DEA on the reason why they need 8 quota.</p> <p>9 Q. What is the -- is it fair to say 10 that one of the purposes of granting 11 procurement quota is to ensure an adequate and 12 uninterrupted supply of medications?</p> <p>13 A. It is one purpose.</p> <p>14 Q. Is it also fair to say that if DEA 15 did not grant procurement quotas, there would 16 be a risk to the adequate and uninterrupted 17 supply of medications?</p> <p>18 MR. CHANDLER: Objection. Vague.</p> <p>19 THE WITNESS: I don't understand the 20 question.</p> <p>21 BY MR. O'CONNOR:</p> <p>22 Q. Okay. Unlike the adequate 23 production quota, procurement quotas are 24 granted on an individual class of controlled 25 substances, correct?</p>	<p style="text-align: right;">Page 49</p> <p>1 may.</p> <p>2 Q. Okay.</p> <p>3 MR. O'CONNOR: I'm going to mark 4 Exhibit 2. (Deposition Exhibit 2 was marked for identification.)</p> <p>5 BY MR. O'CONNOR:</p> <p>6 Q. Do you recognize this document?</p> <p>7 A. Yes.</p> <p>8 Q. What is it?</p> <p>9 A. It is a page from the C.F.R.</p> <p>10 Q. Okay. Was this a portion of the 11 C.F.R. that you used in connection with your 12 role as unit chief and section chief?</p> <p>13 MR. CHANDLER: Objection. Vague as 14 to time.</p> <p>15 THE WITNESS: I don't understand the 16 question.</p> <p>17 BY MR. O'CONNOR:</p> <p>18 Q. Okay. When you were working on 19 quota issues, did you ever refer to this 20 regulation?</p> <p>21 MR. CHANDLER: Same objection.</p> <p>22 THE WITNESS: Can I have the 23 question back.</p>

<p style="text-align: right;">Page 50</p> <p>1 BY MR. O'CONNOR:</p> <p>2 Q. Sure. When you were working on 3 quota issues, did you ever refer to this 4 regulation?</p> <p>5 A. When I was working on the aggregate 6 production quota, then this section that you 7 printed, yes.</p> <p>8 Q. And specifically, I would like to 9 talk about Section 1303.11(b), which says: "In 10 making this determination, the administrator 11 shall consider the following factors."</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And then it goes on to list 15 five items.</p> <p>16 The first is: "Total net disposal 17 of the class by all manufacturers during the 18 current and two preceding years."</p> <p>19 Did DEA consider that factor when 20 setting the aggregate production quotas between 21 1995 and 2018?</p> <p>22 A. Yes.</p> <p>23 Q. And what does it mean to say the 24 "total net disposal of the class?"</p> <p>25 A. So total net disposal would be the</p>	<p style="text-align: right;">Page 52</p> <p>1 they have manufactured a substance but had not 2 disposed of it.</p> <p>3 Q. Okay. And did the DEA take that 4 into account each year between 1995 and 2018 5 when setting the aggregate production quota?</p> <p>6 A. Yes.</p> <p>7 Q. No. 4 says: "Projected demand for 8 such class as indicated by procurement quotas 9 requested pursuant to Section 1303.12."</p> <p>10 What does that mean?</p> <p>11 A. Projected demand would be the amount 12 of material being requested through procurement 13 quotas.</p> <p>14 Q. And did the DEA consider that factor 15 each year in setting aggregate production 16 quota?</p> <p>17 A. Yes.</p> <p>18 Q. No. 5 says: "Other factors 19 affecting medical, scientific research and 20 industrial needs in the United States and 21 lawful export requirements as the administrator 22 finds relevant."</p> <p>23 What other factors did DEA consider 24 when setting the aggregate production quota?</p> <p>25 MR. CHANDLER: Objection. Form.</p>
<p style="text-align: right;">Page 51</p> <p>1 aggregate disposal disposition of all the 2 manufacturers, not counting their manufacturing 3 losses or their returns to other manufacturers.</p> <p>4 Q. Okay. Okay. No. 2 says: "Trends 5 in the national rate of net disposal of the 6 class."</p> <p>7 What does that mean?</p> <p>8 A. Trends in national rate would be 9 changes in disposal rates.</p> <p>10 Q. How would DEA take into account 11 trends in the national rate of net disposal 12 when determining aggregate production quotas?</p> <p>13 A. The main factor would be from FDA.</p> <p>14 Q. Okay. And in each year from 1995 to 15 2018, did DEA, in fact, consider the trends in 16 the national rate of net disposal of the class 17 when setting aggregate production quotas?</p> <p>18 A. Yes.</p> <p>19 Q. No. 3 says: "The total actual or 20 estimated inventories of the class and of all 21 substances manufactured from the class and 22 trends in inventory accumulation."</p> <p>23 What does that mean?</p> <p>24 A. Total inventory would be the amount 25 that the manufacturers have remaining after</p>	<p style="text-align: right;">Page 53</p> <p>1 THE WITNESS: It would depend on the 2 substance.</p> <p>3 BY MR. O'CONNOR:</p> <p>4 Q. So by way of example of oxycodone, 5 what other factors contemplated by Subsection 5 6 did the DEA consider when setting aggregate 7 production quota?</p> <p>8 MR. CHANDLER: Objection. Vague.</p> <p>9 THE WITNESS: It would be the number 10 of manufacturers, their actual use and need for 11 the material, known diversion, known abuse.</p> <p>12 BY MR. O'CONNOR:</p> <p>13 Q. And were those factors you just 14 listed considered every year between 1995 and 15 2018?</p> <p>16 MR. ELSNER: Objection.</p> <p>17 THE WITNESS: When there was data, 18 yes.</p> <p>19 BY MR. O'CONNOR:</p> <p>20 Q. Were there any years in which there 21 was not data on those factors you named?</p> <p>22 MR. CHANDLER: Objection. Vague.</p> <p>23 Scope.</p> <p>24 THE WITNESS: I didn't memorize 25 every year so I don't know.</p>

<p style="text-align: right;">Page 54</p> <p>1 BY MR. O'CONNOR:</p> <p>2 Q. But speaking here today with respect 3 to the DEA practices on setting quota, were 4 there any years in which DEA did not consider 5 the number of manufacturers when setting 6 aggregate production quota?</p> <p>7 MR. CHANDLER: Objection. Vague. 8 Scope.</p> <p>9 THE WITNESS: It's a factor to be 10 considered.</p> <p>11 BY MR. O'CONNOR:</p> <p>12 Q. Were there any years between 1995 13 and 2018 when DEA did not consider the actual 14 use and need for the material?</p> <p>15 A. It is still --</p> <p>16 MR. CHANDLER: Objection. Vague. 17 Scope.</p> <p>18 You can answer.</p> <p>19 THE WITNESS: It is still a factor.</p> <p>20 BY MR. O'CONNOR:</p> <p>21 Q. Were there any years in which DEA 22 did not consider known diversion when 23 determining the aggregate production quota?</p> <p>24 MR. CHANDLER: Objection. Vague. 25 Scope.</p>	<p style="text-align: right;">Page 56</p> <p>1 yes.</p> <p>2 Q. And in each year from 1995 to 2018, 3 did DEA consider the potential disruptions to 4 production when setting the aggregate 5 production quota?</p> <p>6 MR. CHANDLER: Objection. Vague.</p> <p>7 THE WITNESS: It's -- it can be 8 considered when it's known. Potential is not 9 known.</p> <p>10 BY MR. O'CONNOR:</p> <p>11 Q. If there was, for example, a recall 12 in the marketplace of a particular kind of 13 drug, would DEA consider that when setting the 14 aggregate production quota?</p> <p>15 A. If the recall was verified through 16 FDA, then yes.</p> <p>17 Q. Who at DEA was responsible for 18 communicating with FDA regarding aggregate 19 production quota?</p> <p>20 A. The DEA sends a letter signed by Mr. 21 Rannazzisi to FDA requesting that information.</p> <p>22 Q. On the occasions that Mr. Rannazzisi 23 requested the information, did FDA respond?</p> <p>24 A. Yes, in a letter form back.</p> <p>25 Q. Would DEA consider those letters</p>
<p style="text-align: right;">Page 55</p> <p>1 THE WITNESS: It's still a factor.</p> <p>2 BY MR. O'CONNOR:</p> <p>3 Q. And were there any years between 4 1995 and 2018 in which DEA did not consider 5 known abuse when setting aggregate production 6 quota?</p> <p>7 MR. CHANDLER: Objection. Vague. 8 Scope.</p> <p>9 THE WITNESS: True abuse lay with 10 the FDA so it's a factor once again.</p> <p>11 BY MR. O'CONNOR:</p> <p>12 Q. Between 1998 and 2018, did the DEA 13 consider changes in the currently accepted 14 medical use and treatment with the class when 15 considering or setting the aggregate production 16 quota?</p> <p>17 A. As set forth by FDA, yes.</p> <p>18 Q. Between 1995 and 2018, did DEA 19 consider the economic and physical availability 20 of raw materials for use in manufacturing --</p> <p>21 MR. CHANDLER: Objection. Vague.</p> <p>22 BY MR. O'CONNOR:</p> <p>23 Q. -- when setting the aggregate 24 production quota?</p> <p>25 A. When provided with that information,</p>	<p style="text-align: right;">Page 57</p> <p>1 from FDA when making a decision on aggregate 2 production quota?</p> <p>3 A. Yes.</p> <p>4 MR. O'CONNOR: We have been going a 5 little over an hour. Should we take a break?</p> <p>6 THE VIDEOGRAPHER: We are going off 7 the record. This is the end of Media Unit No. 8 1. The time is 10:23. (A short recess was taken.)</p> <p>10 THE VIDEOGRAPHER: We are back on 11 the record. This is the beginning of Media 12 Unit No. 2. The time is 10:57.</p> <p>13 You may proceed, Counsel.</p> <p>14 MR. O'CONNOR: Thank you. I'm going 15 to mark Exhibit 3. (Deposition Exhibit 3 was marked for identification.)</p> <p>18 BY MR. O'CONNOR:</p> <p>19 Q. Ms. Harper-Avilla, are you familiar 20 with this document?</p> <p>21 A. I'm aware of this document.</p> <p>22 Q. Have you seen it before?</p> <p>23 A. I have.</p> <p>24 Q. Would you mind turning to Page 10. On Page 10, the report reads in</p>

<p style="text-align: right;">Page 58</p> <p>1 part: "In establishing APQs for each basic 2 class of Schedule I and Schedule II controlled 3 substances, DEA considers information from many 4 sources, including," and then it lists several 5 sources of information.</p> <p>6 First of all, would you agree with 7 the statement that in setting aggregate 8 production quotas, DEA considers information 9 from many sources?</p> <p>10 A. Yes.</p> <p>11 Q. I just want to walk through each of 12 these bullets.</p> <p>13 In setting the aggregate production 14 quota, does DEA consider manufacturer's 15 production history and anticipated needs?</p> <p>16 A. As provided to DEA, yes.</p> <p>17 Q. And does DEA consider in determining 18 aggregate production quota estimates from IMS 19 Health on retail consumption based on 20 prescriptions dispensed?</p> <p>21 A. Yes.</p> <p>22 Q. In each year from 1995 through 2018, 23 did DEA consider information from IMS Health on 24 retail consumption based on prescriptions 25 dispensed when setting aggregate production</p>	<p style="text-align: right;">Page 60</p> <p>1 Q. Did you use it last year? 2 A. IMS Health no longer exists. 3 Q. Okay. Did the DEA obtain any data 4 to use in its place? 5 MR. ELSNER: Objection. 6 MR. CHANDLER: Objection. Vague. 7 THE WITNESS: DEA has a contract 8 with another vendor, yes. 9 BY MR. O'CONNOR: 10 Q. Which vendor is that? 11 A. IQVIA. 12 Q. And does IQVIA provides estimates on 13 retail consumption based on prescriptions 14 dispensed? 15 A. Yes. 16 Q. When you became unit chief in 2008, 17 did DEA use IMS data on retail consumption 18 based on prescriptions dispensed when setting 19 the aggregate production quota? 20 A. Yes. 21 Q. And in every year between 2008 and 22 the time when DEA switched to IQVIA data, did 23 DEA use IMS Health data when setting the 24 aggregate production quota? 25 MR. ELSNER: Objection.</p>
<p style="text-align: right;">Page 59</p> <p>1 quotas?</p> <p>2 A. For the years that IMS Health was in 3 existence, yes. I don't know what was used 4 prior to that.</p> <p>5 Q. Okay. During which years was IMS 6 Health used?</p> <p>7 MR. ELSNER: Objection.</p> <p>8 THE WITNESS: For the years in which 9 they had a contract with DEA.</p> <p>10 BY MR. O'CONNOR:</p> <p>11 Q. What years were those?</p> <p>12 A. I am not in charge of contracts. I 13 don't know the answer.</p> <p>14 Q. Okay. But in connection with the 15 DEA's practice of setting aggregate production 16 quota, during what years did DEA use estimates 17 from IMS Health on retail consumption based on 18 prescriptions dispensed?</p> <p>19 MR. ELSNER: Objection.</p> <p>20 THE WITNESS: For the years in which 21 DEA had a contract with IMS Health, I am not 22 familiar with these -- those years.</p> <p>23 BY MR. O'CONNOR:</p> <p>24 Q. Can you provide an estimate?</p> <p>25 A. No.</p>	<p style="text-align: right;">Page 61</p> <p>1 THE WITNESS: Yes. 2 BY MR. O'CONNOR: 3 Q. So just to be clear, in the years 4 2009, '10, '11, '12, '13, '14, '15, '16 and 5 '17, DEA used IMS Health data on retail 6 consumption based on prescriptions dispensed 7 when determining the aggregate production 8 quota?</p> <p>9 MR. CHANDLER: Objection. Misstates 10 prior testimony.</p> <p>11 THE WITNESS: Because I'm not aware 12 of when the contract changed, I'm not sure 13 which year IMS Health ceased to exist and 14 became IQVIA.</p> <p>15 BY MR. O'CONNOR:</p> <p>16 Q. But in every year between 2008 and 17 2018, DEA used data either from IMS or IQVIA 18 when setting the annual production quota, 19 correct?</p> <p>20 A. It was a factor and consideration, 21 yes.</p> <p>22 Q. And prior to 2008, did DEA consider 23 IMS Health data when setting the aggregate 24 production quota?</p> <p>25 A. If the contract existed, yes, it</p>

<p style="text-align: right;">Page 62</p> <p>1 did.</p> <p>2 Q. And were there any years in which</p> <p>3 you believe the contract did not exist between</p> <p>4 1995 and 2008?</p> <p>5 A. I don't know when IMS Health came</p> <p>6 into existence so I cannot speak to that.</p> <p>7 Q. During the years in which DEA used</p> <p>8 IMS Health data or IQVIA data, did it use that</p> <p>9 data when setting the aggregate production</p> <p>10 quota for oxycodone?</p> <p>11 MR. CHANDLER: Objection. Scope.</p> <p>12 THE WITNESS: The estimate was a</p> <p>13 factor, a single factor in a multi-factor</p> <p>14 system.</p> <p>15 BY MR. O'CONNOR:</p> <p>16 Q. And during the years in which DEA</p> <p>17 used IMS Health data or IQVIA data, did it use</p> <p>18 that data when setting the aggregate production</p> <p>19 quota for Hydrocodone?</p> <p>20 MR. CHANDLER: Objection. Scope.</p> <p>21 THE WITNESS: It was a factor in it.</p> <p>22 BY MR. O'CONNOR:</p> <p>23 Q. And during the years in which DEA</p> <p>24 used IMS Health data or IQVIA data, did it use</p> <p>25 that data when setting the aggregate production</p>	<p style="text-align: right;">Page 64</p> <p>1 MR. CHANDLER: Objection. Scope.</p> <p>2 THE WITNESS: Only for domestic</p> <p>3 prescription data, yes.</p> <p>4 BY MR. O'CONNOR:</p> <p>5 Q. And they considered that in every</p> <p>6 year from at least 2008 to the present,</p> <p>7 correct?</p> <p>8 MR. CHANDLER: Objection. Scope.</p> <p>9 THE WITNESS: Prescription data</p> <p>10 would be considered as a one point, one single</p> <p>11 factor in a multi-factored system, yes.</p> <p>12 BY MR. O'CONNOR:</p> <p>13 Q. And it would be considered in each</p> <p>14 and every year between 2008 and 2018, correct?</p> <p>15 MR. CHANDLER: Objection. Scope.</p> <p>16 THE WITNESS: If the data existed.</p> <p>17 BY MR. O'CONNOR:</p> <p>18 Q. Were there any years between 2008</p> <p>19 and 2018 in which the data did not exist?</p> <p>20 MR. ELSNER: Objection.</p> <p>21 THE WITNESS: When FDA changed</p> <p>22 treatment marketing, then the data did not</p> <p>23 exist.</p> <p>24 BY MR. O'CONNOR:</p> <p>25 Q. What do you mean by that?</p>
<p style="text-align: right;">Page 63</p> <p>1 quota for every other basic class of controlled</p> <p>2 substances for which quota was granted?</p> <p>3 MR. CHANDLER: Objection. Scope.</p> <p>4 THE WITNESS: Can I have the</p> <p>5 question again.</p> <p>6 BY MR. O'CONNOR:</p> <p>7 Q. Sure. During the years in which DEA</p> <p>8 used IMS Health data or IQVIA data, did it use</p> <p>9 that data when setting the aggregate production</p> <p>10 quota for every other basic class of controlled</p> <p>11 substances for which quota was granted?</p> <p>12 A. No.</p> <p>13 Q. For which classes of controlled</p> <p>14 substances did DEA not use IMS Health or IQVIA</p> <p>15 data when setting the aggregate production</p> <p>16 quota?</p> <p>17 MR. CHANDLER: Objection. Scope.</p> <p>18 THE WITNESS: For those that are not</p> <p>19 FDA approved.</p> <p>20 BY MR. O'CONNOR:</p> <p>21 Q. But for all those classes of</p> <p>22 controlled substances that are FDA approved,</p> <p>23 DEA considered IMS Health or IQVIA data when</p> <p>24 setting the aggregate production quota,</p> <p>25 correct?</p>	<p style="text-align: right;">Page 65</p> <p>1 A. If FDA decided that something needed</p> <p>2 to be pulled from the market, then it did not</p> <p>3 exist. If FDA decided that they were granting</p> <p>4 a new product to the market, the data did not</p> <p>5 exist.</p> <p>6 Q. Okay. But for those classes of</p> <p>7 controlled substances that were already on the</p> <p>8 market, the DEA considered IMS Health data or</p> <p>9 IQVIA data in each and every year between 2008</p> <p>10 and 2018 when determining aggregate production</p> <p>11 quota, correct?</p> <p>12 MR. CHANDLER: Objection. Scope.</p> <p>13 THE WITNESS: If the FDA pulled a</p> <p>14 product in the middle of the year, then no, we</p> <p>15 could not consider already granted prescription</p> <p>16 data foreset [sic] in the next year.</p> <p>17 BY MR. O'CONNOR:</p> <p>18 Q. Were there any products that you can</p> <p>19 recall that were pulled mid-year?</p> <p>20 A. Yes.</p> <p>21 Q. What were those?</p> <p>22 A. Can I have a moment, please, with my</p> <p>23 attorney?</p> <p>24 Q. You can answer the question unless</p> <p>25 you have a question about privilege.</p>

<p style="text-align: right;">Page 66</p> <p>1 MR. CHANDLER: Is there a question 2 of communication or privilege? 3 Go off the record for a minute. 4 MR. O'CONNOR: Sure. 5 THE VIDEOGRAPHER: We are going off 6 the record. The time is 11:00. 7 (A short recess was taken.) 8 THE VIDEOGRAPHER: We are back on 9 the record. The time is 11:06. 10 You may proceed, Counsel. 11 BY MR. O'CONNOR: 12 Q. So Ms. Harper-Avilla, when we left, 13 I think you were -- needed to consult with your 14 attorney. 15 Do you have an answer to the 16 question? 17 A. Can I have the question back, 18 please. 19 Q. We will strike that question. 20 Take a look at the next bullet point 21 on the list. 22 It says: "Data from DEA's internal 23 system for tracking controlled substances 24 transactions known as the Automation of Reports 25 and Consolidated Order System, ARCOS."</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. Were there any years in which you 2 understood the ARCOS data to be invalid? 3 MR. ELSNER: Objection. 4 MR. CHANDLER: Objection. 5 And I will instruct the witness not 6 to answer. 7 You can ask about the quota 8 section's use of ARCOS data, but as far as the 9 validity or operation of ARCOS, no, we will 10 oppose that. 11 BY MR. O'CONNOR: 12 Q. When considering the aggregate 13 production quota, were there any years in which 14 DEA did not rely on ARCOS data for a particular 15 substance? 16 A. The data was considered, but it is a 17 factor. 18 Q. And the data was considered in each 19 and every year between 1995 and 2018, correct? 20 A. Within its known limitations of the 21 data, yes. 22 Q. And it was considered for each and 23 every opioid product for which quota was 24 granted during those years, correct? 25 A. Within the limitations, yes.</p>
<p style="text-align: right;">Page 67</p> <p>1 Did DEA consider data from ARCOS in 2 each year between 1995 and 2018 when 3 determining the aggregate production quota? 4 A. Yes. 5 Q. And did it use data from ARCOS in 6 determining the aggregate production quota in 7 each of those years for every opioid product 8 for which it granted quota? 9 A. Where it was known that the data was 10 valid, yes. 11 Q. Were there any products for which 12 the data was not valid in any of those years 13 between 1995 and 2018? 14 MR. ELSNER: Objection. 15 THE WITNESS: The data is only as 16 good as the manufacturers put into it and there 17 were errors with that in some cases. 18 BY MR. O'CONNOR: 19 Q. Where does the data from ARCOS come 20 from? 21 MR. CHANDLER: Objection. 22 I'm going to instruct the witness 23 not to answer. She is not designated to 24 testify about ARCOS. 25 BY MR. O'CONNOR:</p>	<p style="text-align: right;">Page 69</p> <p>1 Q. And what are those limitations? 2 A. That the data may not always be 3 valid because of a manufacturing input. 4 Q. Were there any years when you did 5 not feel comfortable considering that data 6 because you believed it was unreliable? 7 A. The data was always considered 8 suspect for each year. 9 Q. What do you mean when you say, "it 10 was considered suspect?" 11 A. That the data was only as good as 12 the input from the manufacturers. 13 Q. The next bullet says: "Past history 14 of the quota granted for each substance from 15 YERS/QMS." 16 What is YERS/QMS? 17 A. It's a year-end reporting system, 18 quota management system. 19 Q. That's maintained by DEA? 20 A. Yes. 21 Q. And what data does it include? 22 A. Manufacturing and disposition data 23 for manufacturers who are registered for 24 Schedule I and II controlled substances as well 25 as internationally controlled III through V.</p>

<p style="text-align: right;">Page 70</p> <p>1 Q. Okay. The next bullet says: 2 "Estimates of the projected medical, scientific 3 and reserve stock needs provided by FDA's 4 controlled substances staff."</p> <p>5 Were such estimates considered when 6 determining the aggregate production quota?</p> <p>7 A. For every year that a letter 8 existed, yes.</p> <p>9 Q. And between the years 1995 and 2018, 10 are you aware of any years in which FDA did not 11 provide a letter?</p> <p>12 A. I am not aware.</p> <p>13 Q. And did DEA consider the estimates 14 provided by FDA when determining the aggregate 15 production quota of each and every opioid 16 product for which it granted quota?</p> <p>17 A. Yes.</p> <p>18 Q. How would DEA receive estimates of 19 the projected medical, scientific and reserve 20 stock needs from the FDA?</p> <p>21 A. In a letter.</p> <p>22 Q. The same letter, same type of letter 23 you mentioned earlier today?</p> <p>24 A. It's the exact letter.</p> <p>25 MR. O'CONNOR: Counsel, I don't know</p>	<p style="text-align: right;">Page 72</p> <p>1 THE WITNESS: FDA's projected 2 medical, scientific needs did not include 3 manufacturing needs in terms of yield and 4 losses from the manufacturers. DEA had to 5 consider that in order to reach that estimate.</p> <p>6 BY MR. O'CONNOR:</p> <p>7 Q. So in addition to the estimates 8 provided by FDA, the DEA also considered the 9 amounts needed to account for yield or loss in 10 production?</p> <p>11 A. Yes.</p> <p>12 Q. Is that fair?</p> <p>13 Okay. And is it fair to say that 14 under the regulations regarding quota, DEA was 15 responsible for setting quota at a level that 16 was consistent with the medical, scientific and 17 industrial needs of the United States?</p> <p>18 A. Yes. And the reserve stock.</p> <p>19 Q. The last bullet says: "Data on the 20 diversion of controlled substances, such as 21 information from case seizures and national 22 databases of drug evidence."</p> <p>23 Did the DEA consider that data when 24 establishing aggregate production quota in each 25 and every year between 1995 and 19 -- or in</p>
<p style="text-align: right;">Page 71</p> <p>1 that we received those letters but we make a 2 request on the record to get them.</p> <p>3 MR. CHANDLER: Okay. We can discuss 4 that afterwards.</p> <p>5 BY MR. O'CONNOR:</p> <p>6 Q. And did the DEA consider any other 7 estimates of the projected medical, scientific 8 and reserve stock needs besides the ones 9 provided by FDA when determining aggregate 10 production quota?</p> <p>11 A. Yes. Those provided by the 12 companies themselves.</p> <p>13 Q. In addition to estimates provided to 14 the DEA of the projected medical, scientific 15 and reserve stock needs, did DEA come to its 16 own determination of the projected medical, 17 scientific and reserve stock needs when 18 considering aggregate production quota?</p> <p>19 A. DEA took into account the 20 manufacturing needs in order to make those 21 projected accounts from FDA.</p> <p>22 Q. I'm sorry. I'm not sure I 23 understand the answer.</p> <p>24 Could you just explain?</p> <p>25 MR. ELSNER: Objection.</p>	<p style="text-align: right;">Page 73</p> <p>1 2018?</p> <p>2 MR. ELSNER: Objection.</p> <p>3 THE WITNESS: When the data was 4 available, yes.</p> <p>5 BY MR. O'CONNOR:</p> <p>6 Q. During which years between 1995 and 7 2018, did DEA not consider data on the 8 diversion of controlled substances when setting 9 the aggregate production quota?</p> <p>10 MR. ELSNER: Objection.</p> <p>11 THE WITNESS: When the data was not 12 available.</p> <p>13 BY MR. O'CONNOR:</p> <p>14 Q. In what years was the data not 15 available?</p> <p>16 MR. ELSNER: Objection.</p> <p>17 THE WITNESS: When the case was 18 still open against a manufacturer.</p> <p>19 BY MR. O'CONNOR:</p> <p>20 Q. So let's talk for a moment about 21 what data on diversion of controlled substances 22 was considered.</p> <p>23 When setting the aggregate 24 production quotas, what data on diversion did 25 the agency use?</p>

<p style="text-align: right;">Page 74</p> <p>1 A. Internal data.</p> <p>2 Q. What sorts of internal data?</p> <p>3 A. Known quantifiable seizure data,</p> <p>4 known quantifiable information received from</p> <p>5 state and local law enforcement agencies or</p> <p>6 labs.</p> <p>7 Q. And to the extent DEA had data on</p> <p>8 diversion that was quantifiable, did it</p> <p>9 consider that data in connection with setting</p> <p>10 the aggregate production quotas for opioids?</p> <p>11 A. Yes.</p> <p>12 Q. Did it consider that data in setting</p> <p>13 the aggregate production quota for opioids in</p> <p>14 each and every year between 1995 and 2018?</p> <p>15 A. Where it existed, yes.</p> <p>16 Q. Were there any years during that</p> <p>17 time period where, to your knowledge, the data</p> <p>18 did not exist?</p> <p>19 MR. CHANDLER: Objection. Vague.</p> <p>20 You can answer.</p> <p>21 THE WITNESS: There are years where</p> <p>22 the data was not broken out by controlled</p> <p>23 substance, so we could not quantify it per</p> <p>24 controlled substance, and that led to other</p> <p>25 issues.</p>	<p style="text-align: right;">Page 76</p> <p>1 considered.</p> <p>2 Q. Are you aware of any year between</p> <p>3 1995 and 2018 in which diversion data regarding</p> <p>4 Hydrocodone was not considered when setting the</p> <p>5 Hydrocodone aggregate production quota?</p> <p>6 MR. ELSNER: Objection.</p> <p>7 THE WITNESS: I'm not aware of when</p> <p>8 it was not considered.</p> <p>9 BY MR. O'CONNOR:</p> <p>10 Q. Are you aware of any year between</p> <p>11 1995 and 2018 in which diversion data regarding</p> <p>12 any other opioid product was not considered</p> <p>13 when setting aggregate production quotas?</p> <p>14 A. I am not aware, if it's spelled out</p> <p>15 a controlled substance, then we considered it.</p> <p>16 Q. So to be clear, was there any year</p> <p>17 between 1995 and 2018 in which DEA did not</p> <p>18 consider diversion data involving any other</p> <p>19 opioid product when setting aggregate</p> <p>20 production quotas?</p> <p>21 MR. ELSNER: Objection.</p> <p>22 THE WITNESS: DEA considered</p> <p>23 diversion data when it was a specific</p> <p>24 controlled substance, not a vague term opioid.</p> <p>25 BY MR. O'CONNOR:</p>
<p style="text-align: right;">Page 75</p> <p>1 BY MR. O'CONNOR:</p> <p>2 Q. Where the data could not be broken</p> <p>3 out by controlled substance, did the DEA still</p> <p>4 consider that information when setting</p> <p>5 aggregate production quota?</p> <p>6 A. It could not be attributed to a</p> <p>7 specific controlled substance, so no.</p> <p>8 Q. In what years did the data not allow</p> <p>9 the diversion data to be attributed to a</p> <p>10 particular substance?</p> <p>11 MR. ELSNER: Objection.</p> <p>12 THE WITNESS: It varied in the years</p> <p>13 based on how the data was submitted to DEA.</p> <p>14 Once again, it's not our internal data.</p> <p>15 BY MR. O'CONNOR:</p> <p>16 Q. And who were you receiving the data</p> <p>17 from?</p> <p>18 A. It would have been state and local</p> <p>19 labs.</p> <p>20 Q. Are you aware of any year between</p> <p>21 '95 -- 1995 and 2018 in which diversion data</p> <p>22 regarding oxycodone was not considered when</p> <p>23 setting the oxycodone aggregate production</p> <p>24 quota?</p> <p>25 A. I am not aware when it was not</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. Okay. But when DEA had data on</p> <p>2 those specific opioids, it considered that</p> <p>3 diversion data when setting the aggregate</p> <p>4 production quota, correct?</p> <p>5 A. Yes, if we have the data.</p> <p>6 Q. And during what years did DEA not</p> <p>7 have the data?</p> <p>8 A. I don't recall.</p> <p>9 Q. Do you recall any year in which DEA</p> <p>10 did not have that data?</p> <p>11 MR. ELSNER: Objection.</p> <p>12 THE WITNESS: There were -- there</p> <p>13 was a time frame where the data was not</p> <p>14 specific to the controlled substance. It was</p> <p>15 just termed opioid or termed narcotic, and in</p> <p>16 which case, we could not consider it for the</p> <p>17 individual scope.</p> <p>18 BY MR. O'CONNOR:</p> <p>19 Q. During what years or what time frame</p> <p>20 did you receive the data that was just termed</p> <p>21 opioid or narcotic and not broken out by</p> <p>22 individual molecule?</p> <p>23 A. There are various times. I don't</p> <p>24 recall specific ones.</p> <p>25 Q. So you recall no specific times in</p>

<p style="text-align: right;">Page 78</p> <p>1 which the data wasn't broken out?</p> <p>2 MR. ELSNER: Objection.</p> <p>3 MR. CHANDLER: Objection. Scope.</p> <p>4 BY MR. O'CONNOR:</p> <p>5 Q. You can answer the question.</p> <p>6 A. The data was whatever it was at the time. If it was broken out by controlled substance, we had it. If it was just termed narcotic, we could not use it for the specific controlled substance, and that could occur at any point in time because we did not input the data, that came from state and local labs.</p> <p>13 Q. Okay. If we had to find out which years DEA wasn't able to use the individualized data, how would we do that?</p> <p>16 MR. CHANDLER: Objection. Scope.</p> <p>17 THE WITNESS: I'm not sure. I don't know.</p> <p>19 BY MR. O'CONNOR:</p> <p>20 Q. Is there anyone else at DEA who might know the answer to that question?</p> <p>22 MR. ELSNER: Objection.</p> <p>23 THE WITNESS: I don't know.</p> <p>24 BY MR. O'CONNOR:</p> <p>25 Q. Is there a particular process that</p>	<p style="text-align: right;">Page 80</p> <p>1 Federal Register, who at DEA needs to approve the aggregate production quota numbers?</p> <p>3 A. I don't understand your question.</p> <p>4 Q. Before the aggregate production quota numbers are published in the Federal Register, does someone at the agency have to approve those numbers?</p> <p>8 A. The final approval of those numbers is by the person who signs the Federal Register.</p> <p>11 Q. And who is that in the case of aggregate production quotas?</p> <p>13 A. It would be the administrator or active administrator or the deputy administrator depending on who is in charge at that time.</p> <p>17 Q. Okay. Before the aggregate production quota numbers go to any of the individuals you just mentioned, are there others at DEA that have to sign off first?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Who are those people that need to sign off first?</p> <p>24 A. I don't know the exact list of people who sign off, but it would be the head</p>
<p style="text-align: right;">Page 79</p> <p>1 DEA follows when setting its aggregate production quota for opioid products?</p> <p>3 A. Yes.</p> <p>4 Q. Could you describe that process?</p> <p>5 A. It takes into account all of the steps that you just mentioned earlier.</p> <p>7 Q. And who is involved at DEA in the process?</p> <p>9 A. There are various people in different sections involved in the process.</p> <p>11 Q. Can you give me some examples?</p> <p>12 A. The quota section is involved, the reg writing group is involved, chief counsel is involved. It's various sections within the agency.</p> <p>16 Q. Through that process, the agency determines an aggregate production quota for various individual classes of controlled substances, correct?</p> <p>20 A. In Schedule I and II, yes.</p> <p>21 Q. And those proposed for a proposal for those quotas are then published in the Federal Register; is that correct?</p> <p>24 A. Yes.</p> <p>25 Q. Before they are published in the</p>	<p style="text-align: right;">Page 81</p> <p>1 of diversion, as well as whoever is in the chain between that person and the administrator.</p> <p>4 Q. Okay. When you were --</p> <p>5 MR. CHANDLER: I'm sorry, I will jump in here. Stacy prepared a list of people in the approval chain going back to at least 2011, so I think that would be a good time to work from this, so if you want to testify from that, and we have a copy for you all.</p> <p>11 MR. O'CONNOR: Thank you.</p> <p>12 Appreciate that.</p> <p>13 BY MR. O'CONNOR:</p> <p>14 Q. And Ms. Harper-Avilla, have you reviewed this document before?</p> <p>16 A. Yes.</p> <p>17 Q. And is all the information contained in it accurate?</p> <p>19 A. Yes.</p> <p>20 Q. Okay.</p> <p>21 MR. O'CONNOR: I'm going to mark this Exhibit 4.</p> <p>23 (Deposition Exhibit 4 was marked for identification.)</p> <p>24 BY MR. O'CONNOR:</p>

<p style="text-align: right;">Page 82</p> <p>1 Q. Just so I understand, this document 2 lists the individuals at DEA who were required 3 to review and approve aggregate production 4 quota before it was published in the Federal 5 Register; is that correct?</p> <p>6 A. Yes.</p> <p>7 Q. And while you were unit chief and 8 then section chief, did you also have to 9 approve the quota numbers before they were 10 published in the Federal Register?</p> <p>11 A. Yes.</p> <p>12 Q. During any year in which you 13 approved those numbers, did you feel that they 14 did not reflect the legitimate medical, 15 scientific and industrial needs of the United 16 States?</p> <p>17 MR. CHANDLER: Objection. Scope. 18 THE WITNESS: No. 19 BY MR. O'CONNOR:</p> <p>20 Q. After the proposed aggregate 21 production quotas are published in the Federal 22 Register, do members of the public have an 23 opportunity to comment on them?</p> <p>24 A. Yes.</p> <p>25 Q. So if someone felt that the</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. And who considers that request 2 within the agency?</p> <p>3 A. The UN reporting section does.</p> <p>4 Q. What factors does DEA take into 5 account when deciding whether to grant or how 6 much to grant with respect to individual 7 manufacturing quota?</p> <p>8 A. The factors are laid out in the 9 regulation and we consider those factors.</p> <p>10 Q. Okay. As you sit here today, do you 11 recall what those factors are?</p> <p>12 A. I have the C.F.R. with me, but I 13 don't remember them verbatim.</p> <p>14 Q. Fair enough. Fair enough. Let's 15 take a look at -- see if we can help.</p> <p>16 MR. O'CONNOR: I'm going to mark 17 this as Exhibit 5.</p> <p>18 (Deposition Exhibit 5 was marked for 19 identification.)</p> <p>20 BY MR. O'CONNOR:</p> <p>21 Q. Was this the regulation that you 22 were thinking of a minute ago?</p> <p>23 A. Yes.</p> <p>24 Q. All right. So I am looking at 25 Section 1303.23(a).</p>
<p style="text-align: right;">Page 83</p> <p>1 aggregate production quotas were too high, for 2 example, would they have an opportunity to 3 submit comments to the DEA reflecting that 4 view?</p> <p>5 A. Yes.</p> <p>6 Q. If the DEA received any comments 7 regarding the aggregate production quota, would 8 it take them into account when deciding the 9 final aggregate production quota numbers?</p> <p>10 A. Can I have the question again.</p> <p>11 Q. Sure. If the DEA received any 12 comments regarding the aggregate production 13 quota, would it take them into account when 14 deciding the final aggregate production quota 15 numbers?</p> <p>16 A. Yes.</p> <p>17 Q. Is there a process in place at DEA 18 for determining individual manufacturing 19 quotas?</p> <p>20 A. Yes.</p> <p>21 Q. What is that process?</p> <p>22 A. I don't have it detailed. It's in 23 the C.F.R., but basically, a bulk manufacturer 24 would be required to provide information 25 regarding why they needed that quota.</p>	<p style="text-align: right;">Page 85</p> <p>1 Is that the section that describes 2 the factors DEA considers when determining 3 individual manufacturing quotas?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And in Subsection 2, it says 6 that the individual manufacturing quota can be 7 adjusted "by any other factors which the 8 administrator deems relevant."</p> <p>9 Is that your understanding of the 10 regulation?</p> <p>11 MR. CHANDLER: Objection. Vague. 12 THE WITNESS: I don't understand 13 your question.</p> <p>14 BY MR. O'CONNOR:</p> <p>15 Q. Fair enough. The DEA is permitted 16 to adjust individual manufacturing quotas based 17 on any factor the administrator deems relevant, 18 correct?</p> <p>19 MR. ELSNER: Objection. 20 THE WITNESS: Yes. 21 BY MR. O'CONNOR:</p> <p>22 Q. Among those factors listed here is 23 the extent of any diversion of the controlled 24 substance. 25 Do you see that?</p>

<p style="text-align: right;">Page 86</p> <p>1 A. In Subsection 2?</p> <p>2 Q. Yes.</p> <p>3 MR. CHANDLER: Are we looking at</p> <p>4 (a)(2) or (b)(2)?</p> <p>5 MR. O'CONNOR: (a)(2).</p> <p>6 THE WITNESS: I do not.</p> <p>7 BY MR. O'CONNOR:</p> <p>8 Q. So does the DEA consider, in setting</p> <p>9 individual manufacturing quotas, the extent of</p> <p>10 diversion of a particular controlled substance?</p> <p>11 A. It depends on the manufacturer.</p> <p>12 Q. What do you mean by that?</p> <p>13 A. The CSA and these implemented regs</p> <p>14 were written at a time when most manufacturers</p> <p>15 were vertically integrated from top to bottom</p> <p>16 and put to actual patient pill form, but</p> <p>17 currently, that is not the case for most of the</p> <p>18 manufactures who are applying to be a bulk</p> <p>19 manufacturer. They are applying to provide</p> <p>20 material to a second manufacturer who is then</p> <p>21 authorized to do dosage form to the patient, so</p> <p>22 there is a disconnect apparently between how</p> <p>23 these regs were written and actual business</p> <p>24 practices today. If a manufacturer is</p> <p>25 vertically integrated, then yes, it would be</p>	<p style="text-align: right;">Page 88</p> <p>1 Substances Act, would you grant that quota</p> <p>2 request?</p> <p>3 MR. ELSNER: Objection.</p> <p>4 MR. CHANDLER: Objection. Vague.</p> <p>5 THE WITNESS: The Controlled</p> <p>6 Substances Act is a multipiece document and it</p> <p>7 would depend on what violation they are</p> <p>8 supposedly accused of.</p> <p>9 BY MR. O'CONNOR:</p> <p>10 Q. If the DEA believed that a</p> <p>11 manufacturer did not have effective controls</p> <p>12 against diversion in place, would it grant that</p> <p>13 manufacturer an individual manufacturing quota?</p> <p>14 MR. CHANDLER: Objection. Vague.</p> <p>15 MR. ELSNER: Objection.</p> <p>16 THE WITNESS: Can I have the</p> <p>17 question again.</p> <p>18 BY MR. O'CONNOR:</p> <p>19 Q. Sure. If the DEA believed that a</p> <p>20 manufacturer did not have effective controls</p> <p>21 against diversion in place, would it grant that</p> <p>22 manufacturer an individual manufacturing quota?</p> <p>23 MR. ELSNER: Objection.</p> <p>24 MR. CHANDLER: Same objection.</p> <p>25 THE WITNESS: The DEA has to act on</p>
<p style="text-align: right;">Page 87</p> <p>1 considered.</p> <p>2 Q. Okay. To the extent a manufacturer</p> <p>3 is not vertically integrated, would the DEA</p> <p>4 still consider the extent of diversion of a</p> <p>5 particular controlled substance when</p> <p>6 determining the appropriate individual</p> <p>7 manufacturing quota?</p> <p>8 A. Yes.</p> <p>9 Q. In determining the individual</p> <p>10 manufacturing quota, would the DEA also</p> <p>11 consider whether the manufacturer was complying</p> <p>12 with the Controlled Substances Act?</p> <p>13 A. I don't understand your question.</p> <p>14 Q. If the DEA believed a manufacturer</p> <p>15 was not complying with the Controlled</p> <p>16 Substances Act, would it grant that</p> <p>17 manufacturer an individual manufacturing quota?</p> <p>18 MR. ELSNER: Objection.</p> <p>19 THE WITNESS: I still don't</p> <p>20 understand your question.</p> <p>21 BY MR. O'CONNOR:</p> <p>22 Q. In the course of the approval</p> <p>23 process for an individual manufacturing quota,</p> <p>24 if it came to your attention that the requester</p> <p>25 was not complying with the Controlled</p>	<p style="text-align: right;">Page 89</p> <p>1 more than belief. As a government entity, it</p> <p>2 is fact-based, fact-driven.</p> <p>3 BY MR. O'CONNOR:</p> <p>4 Q. If the DEA was aware of any facts</p> <p>5 that a manufacturer was not maintaining</p> <p>6 effective controls against diversion, would it</p> <p>7 grant that manufacturer an individual</p> <p>8 manufacturing quota?</p> <p>9 MR. ELSNER: Objection.</p> <p>10 MR. CHANDLER: Objection. Form.</p> <p>11 THE WITNESS: Each manufacturer is</p> <p>12 allowed due process until the fact is proven</p> <p>13 with certainty.</p> <p>14 BY MR. O'CONNOR:</p> <p>15 Q. So it's your testimony here today,</p> <p>16 that if you were aware that a manufacturer was</p> <p>17 not maintaining effective controls against</p> <p>18 diversion, you would still grant that</p> <p>19 manufacturer an individual manufacturing quota?</p> <p>20 MR. ELSNER: Objection.</p> <p>21 MR. CHANDLER: Objection. Vague.</p> <p>22 Form generally.</p> <p>23 THE WITNESS: If the DEA had</p> <p>24 knowledge, it would investigate it, and that's</p> <p>25 what would occur in between whether a quota was</p>

<p style="text-align: right;">Page 90</p> <p>1 granted or not.</p> <p>2 BY MR. O'CONNOR:</p> <p>3 Q. And if that investigation determined</p> <p>4 that the manufacturer was not maintaining</p> <p>5 effective controls against diversion, the DEA</p> <p>6 would not grant it a manufacturing quota,</p> <p>7 correct?</p> <p>8 MR. ELSNER: Objection.</p> <p>9 MR. CHANDLER: Objection. Form.</p> <p>10 THE WITNESS: If the DEA had</p> <p>11 evidence and the due process was completed, the</p> <p>12 manufacturer would not be granted quota.</p> <p>13 BY MR. O'CONNOR:</p> <p>14 Q. Okay. I want to turn to procurement</p> <p>15 quota now.</p> <p>16 What does procurement quota refer</p> <p>17 to?</p> <p>18 A. Procurement quota is the quota</p> <p>19 granted for a manufacturer to receive or</p> <p>20 procure aggregate production -- active</p> <p>21 pharmaceutical ingredients, API, from a bulk</p> <p>22 manufacturer, so this is where I talk about the</p> <p>23 fact that the manufacturing process is not</p> <p>24 vertically integrated and bulk manufacturers</p> <p>25 will sell to dosage form manufacturers who are</p>	<p style="text-align: right;">Page 92</p> <p>1 the allocation of procurement quota, correct?</p> <p>2 MR. CHANDLER: Objection. Vague as</p> <p>3 to time.</p> <p>4 BY MR. O'CONNOR:</p> <p>5 Q. You can answer the question.</p> <p>6 A. It does, after the effective date.</p> <p>7 Q. Fair enough. And to your knowledge,</p> <p>8 has this regulation changed significantly in</p> <p>9 the last 20 years?</p> <p>10 MR. CHANDLER: Objection. Vague.</p> <p>11 Scope.</p> <p>12 MR. ELSNER: Objection.</p> <p>13 THE WITNESS: It changed last year.</p> <p>14 BY MR. O'CONNOR:</p> <p>15 Q. Do you know which -- in what way it</p> <p>16 changed?</p> <p>17 MR. ELSNER: Objection.</p> <p>18 BY MR. O'CONNOR:</p> <p>19 Q. Strike that.</p> <p>20 Let's move on. Do you agree with</p> <p>21 the statement in Subsection A that one of the</p> <p>22 purposes of the procurement quota is to ensure</p> <p>23 an adequate and uninterrupted supply of basic</p> <p>24 classes of controlled substances?</p> <p>25 MR. CHANDLER: Objection. Scope.</p>
<p style="text-align: right;">Page 91</p> <p>1 not the same company. Therefore, a procurement</p> <p>2 quota is necessary.</p> <p>3 Q. Fair to say that procurement quota</p> <p>4 is what allows a manufacturer to buy the raw</p> <p>5 material that it needs to produce a dosage</p> <p>6 product?</p> <p>7 A. Correct.</p> <p>8 Q. Okay. Is there a process in place</p> <p>9 at DEA for considering and approving</p> <p>10 procurement quotas?</p> <p>11 A. Yes.</p> <p>12 Q. What is that process?</p> <p>13 A. It depends on the manufacturer's</p> <p>14 business practice and it's written out in the</p> <p>15 C.F.R. under procurement quota.</p> <p>16 Q. Okay.</p> <p>17 MR. O'CONNOR: We will mark this</p> <p>18 Exhibit 6.</p> <p>19 (Deposition Exhibit 6 was marked for</p> <p>20 identification.)</p> <p>21 BY MR. O'CONNOR:</p> <p>22 Q. Are you familiar with this</p> <p>23 regulation?</p> <p>24 A. Yes.</p> <p>25 Q. And it's the regulation that governs</p>	<p style="text-align: right;">Page 93</p> <p>1 THE WITNESS: That's what is written</p> <p>2 there, yes.</p> <p>3 BY MR. O'CONNOR:</p> <p>4 Q. Okay. And in setting procurement</p> <p>5 quotas, do you consider the need to ensure an</p> <p>6 adequate and uninterrupted supply of basic</p> <p>7 classes of controlled substances?</p> <p>8 A. Yes.</p> <p>9 Q. How does the DEA determine how much</p> <p>10 procurement quota to allocate to a particular</p> <p>11 manufacturer?</p> <p>12 A. It depends on the manufacturer's</p> <p>13 business activity on what considerations are</p> <p>14 taken into account.</p> <p>15 Q. What are some of the considerations</p> <p>16 that might be taken into account?</p> <p>17 A. FDA approval.</p> <p>18 Q. Okay.</p> <p>19 A. Manufacturing yields and losses.</p> <p>20 Q. Are there any other factors that DEA</p> <p>21 takes into account when considering how much</p> <p>22 procurement quota to grant?</p> <p>23 A. Yes.</p> <p>24 Q. What are those factors?</p> <p>25 A. Basic market share, FDA recalls.</p>

<p style="text-align: right;">Page 94</p> <p>1 Q. Okay. Are there any other factors, 2 other than those we just discussed, that the 3 DEA considers when setting procurement quota?</p> <p>4 A. Known cases against a manufacturer.</p> <p>5 Q. What do you mean by "known cases?"</p> <p>6 A. We can't consider something we don't 7 know. If there is unfortunately a case going 8 on from another part of DEA that we are not 9 apprised of, then we cannot consider it.</p> <p>10 Q. What do you mean by "a case?"</p> <p>11 A. An investigation.</p> <p>12 Q. If DEA had reason to believe that a 13 manufacturer was causing controlled substances 14 to be diverted, would it grant that 15 manufacturer a procurement quota?</p> <p>16 MR. CHANDLER: Objection.</p> <p>17 THE WITNESS: It would be turned 18 over to the field investigators to determine.</p> <p>19 BY MR. O'CONNOR:</p> <p>20 Q. And if those field investigators 21 determined that the manufacturer was causing 22 controlled substances to be diverted, would it 23 grant that manufacturer a procurement quota?</p> <p>24 MR. CHANDLER: Objection. Vague. 25 Incomplete hypothetical.</p>	<p style="text-align: right;">Page 96</p> <p>1 Unit No. 3. The time is 1:07. 2 You may proceed, Counsel. 3 BY MR. O'CONNOR:</p> <p>4 Q. Welcome back.</p> <p>5 A. Thank you.</p> <p>6 MR. O'CONNOR: I'm going to mark two 7 documents here as Exhibits 7 and 8. 8 (Deposition Exhibit 7 was marked for 9 identification.) 10 (Deposition Exhibit 8 was marked for 11 identification.) 12 BY MR. O'CONNOR: 13 Q. These are documents that appeared on 14 DEA's website. 15 A. Okay. 16 MR. CHANDLER: Just so we are clear, 17 Document 7 is the one updated January 13, 2010; 18 is that right? 19 MR. O'CONNOR: That's correct. 20 MR. CHANDLER: And 8 is the January 21 22nd. 22 MR. O'CONNOR: That's right. 23 BY MR. O'CONNOR: 24 Q. Starting with No. 7, which reflects 25 the aggregate production quota history for</p>
<p style="text-align: right;">Page 95</p> <p>1 MR. ELSNER: Objection.</p> <p>2 THE WITNESS: The manufacturer would 3 still end up going through due process.</p> <p>4 BY MR. O'CONNOR:</p> <p>5 Q. But at the end of the day, if DEA 6 found that that manufacturer was diverting 7 controlled substances or causing them to be 8 diverted, DEA would not give them a procurement 9 quota, correct?</p> <p>10 MR. ELSNER: Objection.</p> <p>11 MR. CHANDLER: Objection. Vague. 12 Incomplete hypothetical.</p> <p>13 THE WITNESS: At the end of due 14 process, if the manufacturer was found to be in 15 violation, then there would be no quota, but 16 during the due process, it is open.</p> <p>17 MR. O'CONNOR: We have gone about 18 another hour. Should we take a break?</p> <p>19 MR. CHANDLER: Okay.</p> <p>20 THE VIDEOGRAPHER: We are going off 21 the record. This is the end of Media Unit No. 22 2. The time is 11:58. 23 (A short recess was taken.)</p> <p>24 THE VIDEOGRAPHER: We are back on 25 the record. This is the beginning of Media</p>	<p style="text-align: right;">Page 97</p> <p>1 selective substances between 2000 and 2010. 2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. Do you recognize this chart?</p> <p>5 A. I recognize the format of the chart, 6 yes.</p> <p>7 Q. Do you agree that it reflects the 8 aggregate production quota history for the 9 substances listed here on the left?</p> <p>10 MR. ELSNER: Objection.</p> <p>11 THE WITNESS: With the exception of 12 2010, it reflects the aggregate production 13 quota as finalized from 2000 to 2009.</p> <p>14 BY MR. O'CONNOR:</p> <p>15 Q. Okay. And with respect to 2010, 16 what does it reflect?</p> <p>17 A. It would reflect the established.</p> <p>18 Q. And is it fair to state the 19 established quota might change over the course 20 of the year?</p> <p>21 A. Correct.</p> <p>22 Q. Let's look at No. 8, Exhibit 8.</p> <p>23 A. Yes.</p> <p>24 Q. And do you agree that this reflects 25 the aggregate production quota history for the</p>

25 (Pages 94 - 97)

<p style="text-align: right;">Page 98</p> <p>1 substances listed on the left between the years 2 2009 through at least 2018?</p> <p>3 A. The final aggregate production 4 quota, yes.</p> <p>5 Q. And I want to direct your attention 6 on Exhibit 7 to the lines that say: "Oxycodone 7 (sale) and oxycodone (CONV)."</p> <p>8 What does oxycodone (sale) mean?</p> <p>9 A. That that is the aggregate 10 production quota set for oxycodone that will go 11 to dosage form manufacturers.</p> <p>12 Q. Okay. And what does oxycodone 13 (CONV) mean?</p> <p>14 A. So CONV stands for conversion and 15 that is the amount of oxycodone that will be 16 converted to a different substance.</p> <p>17 Q. And you agree that the numbers 18 listed to the right of oxycodone (sale) reflect 19 the final aggregate production quota for the 20 years listed in the column headings?</p> <p>21 MR. CHANDLER: Objection. 22 Mischaracterizes prior testimony. 23 THE WITNESS: For 2000 through 2009, 24 yes. 25 BY MR. O'CONNOR:</p>	<p style="text-align: right;">Page 100</p> <p>1 DEA consider all of the factors it was required 2 to consider under the Controlled Substances Act 3 in determining those numbers?</p> <p>4 MR. CHANDLER: Objection. Scope. 5 THE WITNESS: So far as the factors 6 related to that substance, then yes.</p> <p>7 BY MR. O'CONNOR:</p> <p>8 Q. Just to address counsel's objection 9 to scope, with respect to all the numbers 10 listed in Exhibits 7 and 8 that are opioids, 11 did the DEA consider all of the factors that it 12 was required to consider by the Controlled 13 Substances Act?</p> <p>14 A. Where appropriate, yes.</p> <p>15 Q. Were there any instances in which 16 DEA did not consider factors it was required to 17 consider under the Controlled Substances Act?</p> <p>18 A. If there was no data for it, then 19 no, we could not consider it.</p> <p>20 Q. Are there any substances for which 21 there was no data to consider the factors the 22 DEA was required to consider?</p> <p>23 MR. ELSNER: Objection. 24 MR. CHANDLER: Objection. 25 BY MR. O'CONNOR:</p>
<p style="text-align: right;">Page 99</p> <p>1 Q. Okay. So just to make sure I am 2 reading this correctly, if we look in the 3 column 2008, the number is for oxycodone (sale) 4 70,000.</p> <p>5 What does that 70,000 represent?</p> <p>6 A. That 70,000 represents the DEA's 7 estimated final number of the amount of 8 oxycodone for sale that may be required to 9 fulfill legitimate, scientific, medical, 10 research, industrial needs, export as well as 11 inventory requirements.</p> <p>12 Q. Okay. And in coming to that number, 13 did DEA take into account the factors that it 14 was required to consider under the Controlled 15 Substances Act?</p> <p>16 MR. ELSNER: Objection. 17 THE WITNESS: Yes. 18 BY MR. O'CONNOR:</p> <p>19 Q. And in coming to that number, did 20 DEA consider the factors it was required to 21 under the regulation related to aggregate 22 production quota?</p> <p>23 A. Yes.</p> <p>24 Q. And with respect to the numbers 25 listed for the other substances here, did the</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. You can answer.</p> <p>2 A. Yes.</p> <p>3 Q. And which were those?</p> <p>4 A. Alfentanil is only for export so 5 there is not -- the other factors are missing 6 when we do the request.</p> <p>7 Q. So with respect to codeine -- and 8 just to be clear, you said Alfentanil, correct?</p> <p>9 A. Correct.</p> <p>10 Q. I want to make sure the court 11 reporter has that. Thank you.</p> <p>12 With respect to codeine, fentanyl, 13 hydromorphone, levorphanol, methadone, 14 morphine, opium, oxycodone, hydromorphone and 15 sufentanil, are you aware of any year in which 16 the data DEA was required to consider to 17 determine the aggregate production quota was 18 not available?</p> <p>19 A. That list that you mentioned is 20 rather long and I don't remember all the 21 substances so where the substances had data for 22 every single factor, those factors were 23 considered. If there was a place where FDA did 24 not approve or it was not marketed in the U.S., 25 then it could not be considered.</p>

<p style="text-align: right;">Page 102</p> <p>1 Q. With the exception of Alfentanil, 2 which you already mentioned, are there any 3 other products for which DEA did not have the 4 data necessary for it to consider the factors 5 that it's required by statute and regulation to 6 consider in establishing the aggregate 7 production quota?</p> <p>8 MR. CHANDLER: Objection.</p> <p>9 THE WITNESS: There would be places 10 -- there would be substances where DEA could 11 not have full data, yes.</p> <p>12 BY MR. O'CONNOR:</p> <p>13 Q. And which are those substances?</p> <p>14 A. Opium.</p> <p>15 Q. Okay. Are there any other 16 substances for which DEA did not have the data 17 it needed to determine aggregate production 18 quota?</p> <p>19 MR. CHANDLER: Objection.</p> <p>20 THE WITNESS: Yes, there's other 21 places.</p> <p>22 BY MR. O'CONNOR:</p> <p>23 Q. And what are those?</p> <p>24 A. Methadone.</p> <p>25 Q. Okay. What information was lacking</p>	<p style="text-align: right;">Page 104</p> <p>1 MR. CHANDLER: Objection. 2 THE WITNESS: I don't understand the 3 question.</p> <p>4 BY MR. O'CONNOR:</p> <p>5 Q. If you didn't have data from 6 manufacturers, how did you make that decision?</p> <p>7 A. For which?</p> <p>8 Q. Oxycodone.</p> <p>9 A. For which? Our aggregate production 10 quota?</p> <p>11 Q. Yes.</p> <p>12 A. DEA made the decision based on 13 manufacturing data, FDA data as well as other 14 information as required in the CSA. However, 15 DEA bills each year separately so if a 16 manufacturer pulled out of the market, they 17 would not submit that data. However, a new 18 manufacturer may come into the market and have 19 a different weighted value for the market at 20 that time.</p> <p>21 Q. Would you agree that with respect to 22 aggregate production quota for oxycodone, that 23 DEA considered the factors it was legally 24 required to consider?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 103</p> <p>1 with respect to Methadone?</p> <p>2 MR. CHANDLER: Objection.</p> <p>3 THE WITNESS: Methadone is used in 4 narcotics treatment facilities and therefore, 5 it is not always recorded accurately. Therefore, actual usage is not always captured correctly.</p> <p>8 BY MR. O'CONNOR:</p> <p>9 Q. Okay. So for oxycodone, in 10 particular, for each of the years listed here, 11 did DEA consider the factors it was required by statute and regulation to consider in setting the aggregate production quota?</p> <p>14 A. Yes, where data is available, yes.</p> <p>15 Q. Were there any years during which 16 data was not available for oxycodone?</p> <p>17 MR. ELSNER: Objection.</p> <p>18 THE WITNESS: There were years where 19 manufacturers did not submit complete and timely information in order for us to do our work.</p> <p>22 BY MR. O'CONNOR:</p> <p>23 Q. When DEA granted the quota for oxycodone during those years, on what 25 information did it rely?</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. Okay. With respect to 2 Hydromorphone, in each of the years listed 3 here, do you agree that with respect to 4 aggregate production quota, DEA considered the 5 factors it was legally required to consider?</p> <p>6 A. Yes.</p> <p>7 Q. With respect to Hydromorphone -- 8 sorry, strike that.</p> <p>9 With respect to Hydrocodone, in each 10 of the years listed, do you agree that with 11 respect to aggregate production quota, DEA 12 considered the factors it was legally required 13 to consider?</p> <p>14 A. Yes.</p> <p>15 Q. With respect to oxymorphone, in 16 setting the aggregate production quota in each 17 of the years listed, do you agree that DEA 18 considered the factors it was legally required 19 to consider?</p> <p>20 A. Yes.</p> <p>21 Q. With respect to fentanyl, in setting 22 the aggregate production quota for the years 23 listed here, did DEA consider the factors it 24 was legally required to consider?</p> <p>25 A. Yes.</p>

<p style="text-align: right;">Page 106</p> <p>1 Q. With respect to morphine, in setting 2 the aggregate production quota, did DEA 3 consider all of the factors it was legally 4 required to consider?</p> <p>5 A. Yes.</p> <p>6 Q. As a representative of DEA sitting 7 here today, do you believe the DEA is 8 responsible for the numbers that appear on this 9 sheet?</p> <p>10 MR. ELSNER: Objection.</p> <p>11 MR. CHANDLER: Objection. Scope. 12 Vague.</p> <p>13 THE WITNESS: The DEA is known to 14 put the numbers out, yes, correct.</p> <p>15 BY MR. O'CONNOR:</p> <p>16 Q. So you would agree that DEA is 17 responsible for the aggregate production quota 18 set each year for these products?</p> <p>19 MR. CHANDLER: Objection. Scope. 20 Vague.</p> <p>21 MR. ELSNER: Objection.</p> <p>22 THE WITNESS: DEA is required to 23 publish the value, correct, yes.</p> <p>24 BY MR. O'CONNOR:</p> <p>25 Q. DEA also determines the value of the</p>	<p style="text-align: right;">Page 108</p> <p>1 combination products were listed as Schedule 2 III controlled substances, correct?</p> <p>3 A. Yes</p> <p>4 MR. O'CONNOR: Can we take a short 5 break</p> <p>6 THE VIDEOGRAPHER: We are going off 7 the record. The time is 1:25</p> <p>8 (A short recess was taken)</p> <p>9 THE VIDEOGRAPHER: We are back on 10 the record. The time is 1:41</p> <p>11 You may proceed, Counsel</p> <p>12 EXAMINATION BY COUNSEL FOR DEFENDANT MCKESSON 13 BY MR. EPPICH:</p> <p>14 Q. Ms. Harper-Avilla, my name is Chris 15 Eppich. I'm from the law firm of Covington & 16 Burling and I represent McKesson in this 17 matter</p> <p>18 Are you familiar with the 19 distributor defendants in this case?</p> <p>20 A. I know of McKesson</p> <p>21 Q. McKesson and AmerisourceBergen and 22 Cardinal Health?</p> <p>23 A. Yes</p> <p>24 Q. Those are -- I represent those folks 25 today for this portion of your testimony</p>
<p style="text-align: right;">Page 107</p> <p>1 quota for each of these substances, correct?</p> <p>2 MR. CHANDLER: Objection.</p> <p>3 MR. ELSNER: Objection.</p> <p>4 THE WITNESS: DEA is required to 5 provide an estimated value for these 6 substances.</p> <p>7 BY MR. O'CONNOR:</p> <p>8 Q. And the numbers that are ultimately 9 published as the aggregate production quota for 10 each of these substances are determined by DEA, 11 correct?</p> <p>12 MR. CHANDLER: Objection.</p> <p>13 THE WITNESS: With assistance from 14 other agencies, yes.</p> <p>15 BY MR. O'CONNOR:</p> <p>16 Q. Does DEA set an aggregate production 17 quota for the total amount of Hydrocodone that 18 can be manufactured in a given year?</p> <p>19 A. Yes.</p> <p>20 Q. So when Hydrocodone is used in 21 combination product, like Vicodin, the amount 22 of Hydrocodone used counts against the quota 23 amount, correct?</p> <p>24 A. Yes.</p> <p>25 Q. And that was true when Hydrocodone</p>	<p style="text-align: right;">Page 109</p> <p>1 Let me -- let me pick up where Mr. 2 O'Connor just left off. He asked you a 3 question referring to Exhibit 7 and 8.</p> <p>4 He asked you, and I will just read 5 it right from the record. He said: "So just 6 to make sure I am reading this correctly, if we 7 look at the column 2008, the number for 8 oxycodone sales 70,000, what does that 70,000 9 represent?"</p> <p>10 And your testimony, ma'am, your 11 answer: "That 70,000 represents the DEA's 12 estimated final number of the amount of 13 oxycodone for sale that may be required to 14 fulfill legitimate, scientific, medical 15 research, industrial needs as well as inventory 16 requirements."</p> <p>17 Do you remember providing that 18 testimony, ma'am?</p> <p>19 A. Yes.</p> <p>20 Q. And would your answer be the same 21 for every year reflected on Exhibit 7 and 8?</p> <p>22 MR. CHANDLER: Objection. Vague.</p> <p>23 THE WITNESS: It would -- it would 24 be for legitimate medical needs, scientific 25 research, industrial, export as well as</p>

<p style="text-align: right;">Page 110</p> <p>1 inventory needs, yes, and then the 2 manufacturing losses that are necessary to make 3 those final figures.</p> <p>4 BY MR. EPPICH:</p> <p>5 Q. Thank you. And is it also true for 6 every opioid that is listed on Exhibit 7 and 8?</p> <p>7 MR. CHANDLER: Objection. Vague.</p> <p>8 THE WITNESS: It would -- it would 9 work for those that are -- have FDA-approved 10 products. Those that do not, no.</p> <p>11 BY MR. EPPICH:</p> <p>12 Q. And which ones have FDA-approved 13 products, ma'am?</p> <p>14 A. That, I can't -- I couldn't cite all 15 of those.</p> <p>16 Q. Well, oxycodone is one of them, 17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. Hydrocodone?</p> <p>20 A. Yes.</p> <p>21 Q. Hydromorphone?</p> <p>22 A. Yes.</p> <p>23 Q. Morphine?</p> <p>24 A. Yes.</p> <p>25 Q. Fentanyl?</p>	<p style="text-align: right;">Page 112</p> <p>1 that is used to set the quotas, correct?</p> <p>2 MR. ELSNER: Objection.</p> <p>3 MR. CHANDLER: Objection.</p> <p>4 THE WITNESS: The list of companies 5 you just provided do not receive quota and 6 therefore, are not considered for aggregate 7 production quotas.</p> <p>8 BY MR. EPPICH:</p> <p>9 Q. DEA does not consult with wholesale 10 distributors, such as McKesson, Cardinal and 11 AmerisourceBergen when DEA sets the quotas for 12 controlled substances, correct?</p> <p>13 A. Correct.</p> <p>14 Q. And DEA does not consult with 15 pharmacy chains, such as CVS, Walgreens, Rite 16 Aid, Walmart, Giant Eagle, HBC, when DEA sets 17 quotas for controlled substances?</p> <p>18 A. Correct.</p> <p>19 MR. CHANDLER: Objection.</p> <p>20 BY MR. EPPICH:</p> <p>21 Q. Wholesale distributors, such as 22 McKesson, Cardinal, AmerisourceBergen, they do 23 not apply for DEA -- to DEA for quotas, do 24 they?</p> <p>25 MR. CHANDLER: Objection.</p>
<p style="text-align: right;">Page 111</p> <p>1 A. Yes.</p> <p>2 Q. Do any others come to mind after we 3 just reviewed five? Oxymorphone, for example?</p> <p>4 A. Correct.</p> <p>5 Q. Oxy -- I will leave it at that.</p> <p>6 Now, Mr. O'Connor asked you several 7 questions about the information DEA considers 8 in setting the aggregate production quota.</p> <p>9 Do you remember that testimony 10 today?</p> <p>11 A. Yes.</p> <p>12 Q. You testified that DEA sets each of 13 these quotas annually, correct?</p> <p>14 A. Correct.</p> <p>15 Q. Now, do wholesale manufacturers such 16 as McKesson, Cardinal and AmerisourceBergen 17 provide any information to DEA that is used to 18 set those quotas?</p> <p>19 MR. ELSNER: Objection.</p> <p>20 THE WITNESS: Quotas are not related 21 to distributors, so no.</p> <p>22 BY MR. EPPICH:</p> <p>23 Q. And pharmacy chains, such as CVS, 24 Walgreens, Rite Aid, Walmart, Giant Eagle, HBC, 25 they also don't provide any information to DEA</p>	<p style="text-align: right;">Page 113</p> <p>1 THE WITNESS: Correct.</p> <p>2 BY MR. EPPICH:</p> <p>3 Q. And pharmacy chains, such as CVS, 4 Walgreens, Rite Aid, Walmart, Giant Eagle, HBC, 5 they also do not apply to DEA for quotas, 6 correct?</p> <p>7 MR. CHANDLER: Objection. Scope.</p> <p>8 MR. ELSNER: Objection.</p> <p>9 THE WITNESS: Correct.</p> <p>10 BY MR. EPPICH:</p> <p>11 Q. Now, DEA is required by law to 12 establish aggregate production quotas for 13 certain controlled substances, correct?</p> <p>14 A. Correct.</p> <p>15 Q. There are a number of statutes and 16 regulations that govern the process DEA must 17 follow and the considerations DEA must consider 18 in establishing quotas for controlled 19 substances?</p> <p>20 MR. CHANDLER: Objection.</p> <p>21 THE WITNESS: Correct.</p> <p>22 BY MR. EPPICH:</p> <p>23 Q. And DEA endeavors to comply with 24 these statutes and regulations governing the 25 establishment of quotas for controlled</p>

<p>1 substances, correct?</p> <p>2 A. Correct.</p> <p>3 Q. In following these statute and</p> <p>4 regulations, the aggregated production quota</p> <p>5 reflects the estimated medical, scientific</p> <p>6 research and industrial needs of the United</p> <p>7 States, correct?</p> <p>8 A. Along with export requirements and</p> <p>9 inventory requirements and manufacturing yield</p> <p>10 and losses counted in, yes.</p> <p>11 Q. The aggregate production quota is</p> <p>12 the maximum amount of a controlled substance</p> <p>13 that can be manufactured and distributed in a</p> <p>14 year, correct?</p> <p>15 A. It's the maximum amount that can be</p> <p>16 manufactured within a year.</p> <p>17 Q. In setting the quota, the aggregate</p> <p>18 production quota for a prescription opioid, DEA</p> <p>19 understands that pharmaceutical manufacturers</p> <p>20 may manufacture, wholesale distributors may</p> <p>21 distribute, and pharmacies may dispense to</p> <p>22 patients up to the amount the DEA allowed,</p> <p>23 correct?</p> <p>24 MR. CHANDLER: Objection.</p> <p>25 THE WITNESS: I don't understand</p>	<p>Page 114</p> <p>1 estimated need, not the granted need.</p> <p>2 BY MR. EPPICH:</p> <p>3 Q. And so the aggregate production</p> <p>4 quota is the total of all the individual</p> <p>5 manufactured quotas that DEA expect</p> <p>6 manufacturers to manufacture that year?</p> <p>7 MR. CHANDLER: Objection.</p> <p>8 MR. ELSNER: Objection.</p> <p>9 THE WITNESS: It's an estimate.</p> <p>10 BY MR. EPPICH:</p> <p>11 Q. But it's true that DEA understands</p> <p>12 that ultimately, pharmacies may dispense to</p> <p>13 patients across this country, an amount of the</p> <p>14 controlled substance that is set by the</p> <p>15 aggregate production quota, correct?</p> <p>16 MR. ELSNER: Objection.</p> <p>17 MR. CHANDLER: Objection.</p> <p>18 THE WITNESS: A pharmacy may</p> <p>19 dispense an amount needed for legitimate</p> <p>20 patient need.</p> <p>21 BY MR. EPPICH:</p> <p>22 Q. If the DEA increases the aggregate</p> <p>23 production quota for prescription opioids, DEA</p> <p>24 understands that it is allowing more opioids in</p> <p>25 the communities, correct?</p>
<p>1 your question.</p> <p>2 BY MR. EPPICH:</p> <p>3 Q. Well, I am just asking. If DEA sets</p> <p>4 an aggregate production quota, DEA understands</p> <p>5 that the manufacturers may manufacturer up to</p> <p>6 that limit, correct?</p> <p>7 MR. CHANDLER: Objection.</p> <p>8 THE WITNESS: I don't understand</p> <p>9 your question.</p> <p>10 BY MR. EPPICH:</p> <p>11 Q. Let me try again. I will try and</p> <p>12 make it more clear, ma'am.</p> <p>13 In setting the quota --</p> <p>14 A. The aggregate production quota?</p> <p>15 Q. The aggregate production quota, the</p> <p>16 DEA understands that pharmaceutical</p> <p>17 manufacturers, they are going to manufacture</p> <p>18 enough drugs to supply up to that quota amount,</p> <p>19 correct?</p> <p>20 MR. CHANDLER: Objection.</p> <p>21 THE WITNESS: No. So the</p> <p>22 manufacturer, if they are granted an individual</p> <p>23 quota, will manufacture up to that individual</p> <p>24 quota, not up to the APQ. The APQ is the</p> <p>25 aggregate of all manufacturers and it's the</p>	<p>Page 115</p> <p>1 MR. CHANDLER: Objection.</p> <p>2 MR. ELSNER: Objection.</p> <p>3 THE WITNESS: The reason for an</p> <p>4 increase in an aggregate production quota is</p> <p>5 not automatically equated with what goes out to</p> <p>6 the community itself. It could be used for</p> <p>7 scientific and research needs which are</p> <p>8 different and separate from what is seen in --</p> <p>9 for patient needs.</p> <p>10 BY MR. EPPICH:</p> <p>11 Q. How much of the aggregate production</p> <p>12 quota goes to patient needs on a given year?</p> <p>13 MR. CHANDLER: Objection.</p> <p>14 THE WITNESS: I don't know off the</p> <p>15 top of my head.</p> <p>16 BY MR. EPPICH:</p> <p>17 Q. But you would agree with me that</p> <p>18 each time the DEA increases that quota, the</p> <p>19 amount of -- in this case, prescription opioids</p> <p>20 that goes into the community increases?</p> <p>21 MR. CHANDLER: Objection.</p> <p>22 MR. ELSNER: Objection.</p> <p>23 THE WITNESS: I would not -- I would</p> <p>24 suggest that it would go towards a scientific</p> <p>25 or research need perhaps or export need which</p>

<p style="text-align: right;">Page 118</p> <p>1 has nothing to do with domestic communities. 2 BY MR. EPPICH: 3 Q. Do you know or are you guessing when 4 you provide that response? 5 MR. CHANDLER: Objection. 6 MR. ELSNER: Objection. 7 THE WITNESS: It would depend on the 8 year. 9 BY MR. EPPICH: 10 Q. Do you agree that in setting the 11 annual production quota, the DEA has the 12 ability to control the amount of prescription 13 opioids available to the public? 14 MR. CHANDLER: Objection. 15 THE WITNESS: I don't understand the 16 question. 17 BY MR. EPPICH: 18 Q. Well, in setting the annual 19 production quota, would you agree that DEA has 20 the ability to control how much of a 21 prescription opioid is available to the public? 22 MR. CHANDLER: Objection. 23 MR. ELSNER: Objection. 24 THE WITNESS: I would not. 25 BY MR. EPPICH:</p>	<p style="text-align: right;">Page 120</p> <p>1 A. It is not for public consumption. 2 Q. Where do you find that document? 3 MR. ELSNER: Objection. 4 THE WITNESS: Within DEA's internal 5 control. 6 BY MR. EPPICH: 7 Q. Is there a server that it's stored 8 on, is there a bookshelf that it's stored on? 9 A. More than likely a server. 10 Q. You access it electronically is what 11 you are saying? 12 A. It would be. 13 Q. Do you access it? 14 A. I do not because it's the same as 15 the regs in the statute, and therefore, if you 16 can read the regs in the statute, for the most 17 part, the information is there, as well as the 18 FDA letter that comes in. 19 Q. Does your team rely on these 20 standard operating procedures? 21 A. Yes. 22 Q. And where do they go to look for it? 23 Do they know the name of this document? 24 A. I'm sure they do. 25 Q. But you do not sitting here today?</p>
<p style="text-align: right;">Page 119</p> <p>1 Q. Why not? 2 A. Because there are many other factors 3 in between the number that is set and what goes 4 out to the public. 5 Q. What are those factors? 6 A. Manufacturing losses and yield, FDA 7 recalls, FDA changes in market practices, 8 manufacturers losing contracts, among others. 9 Q. We talked a fair amount today about 10 the process by which DEA sets the aggregate 11 production quota. 12 Are there any DEA guides or manuals 13 or written standards of operation procedures 14 explaining the process how DEA sets the annual 15 production quota? 16 A. Yes. 17 Q. And what are those documents called? 18 A. SOPs, standard operating procedures. 19 Q. Is there a specific one that you 20 have in mind for setting the aggregate 21 production quota? 22 A. Not one in mind definitely. 23 Q. There are multiple? 24 A. They -- the document exists. 25 Q. Where would I find that document?</p>	<p style="text-align: right;">Page 121</p> <p>1 A. It is just called SOPs, quota SOPs. 2 Q. Thank you. Earlier today, you 3 testified that you met with Mr. Joe Rannazzisi 4 and Dr. Chris Sannerud, correct? 5 MR. CHANDLER: Objection. 6 THE WITNESS: Correct. 7 BY MR. EPPICH: 8 Q. That was in preparation for your 9 deposition today? 10 A. Yes. 11 Q. And before your preparation sessions 12 with your counsel, when was the last time that 13 you communicated with Mr. Rannazzisi? 14 A. 2015. 15 Q. And when was the last time that you 16 communicated with Ms. Sannerud? 17 A. March perhaps. 18 Q. In your communications with Ms. 19 Sannerud, were those in relation to preparing 20 for the deposition today? 21 A. Not all of those, no. 22 Q. What did you discuss with Ms. 23 Sannerud during those conversations? 24 A. The ones in March? 25 Q. Yes, ma'am.</p>

<p style="text-align: right;">Page 122</p> <p>1 A. The birth of her grandson. 2 Q. You're friends? 3 A. We've worked together for a long 4 time. 5 Q. Are you aware that Mr. Rannazzisi 6 has been subpoenaed to testify in this case? 7 A. Yes. 8 Q. When did you become aware of that? 9 MR. CHANDLER: Objection. Scope. 10 THE WITNESS: Probably last year 11 sometime. 12 BY MR. EPPICH: 13 Q. Are you aware that he will be 14 deposed in the coming weeks? 15 MR. CHANDLER: Objection. Scope. 16 THE WITNESS: No. 17 BY MR. EPPICH: 18 Q. Are you aware that defendants have 19 requested the deposition of Ms. Sannerud in 20 this litigation? 21 MR. CHANDLER: Objection. Scope. 22 THE WITNESS: Yes. 23 BY MR. EPPICH: 24 Q. When did you -- when did you become 25 aware of that?</p>	<p style="text-align: right;">Page 124</p> <p>1 Q. How many -- how many phone calls did 2 you have with Mr. Rannazzisi in preparation for 3 today's deposition? 4 A. One. 5 Q. And how long did that conversation 6 last? 7 A. Approximately an hour. 8 Q. I would like to return to Exhibit 4. 9 Exhibit 4 is the document that I 10 understand you or your counsel prepared titled: 11 "APQ Review and Approval." 12 A. Yes. 13 Q. Did you prepare this document, 14 ma'am? 15 A. I assisted in it. 16 Q. Now, the document starts in 2011, 17 correct? 18 A. Correct. 19 Q. And it identifies in July 2011 -- 20 Joseph T. Rannazzisi is the first name on the 21 list? 22 A. Yes. 23 Q. Does that -- does that indicate that 24 Mr. Rannazzisi was the final approver of the 25 proposed adjustments for 2011?</p>
<p style="text-align: right;">Page 123</p> <p>1 MR. CHANDLER: Same objection. 2 THE WITNESS: Last year sometime. 3 BY MR. EPPICH: 4 Q. Now, earlier today, you were asked 5 who was present during your preparation 6 sessions. 7 Do you remember that? 8 A. Yes. 9 Q. And I believe you responded that 10 counsel for the DOJ was there with you? 11 A. Yes. 12 Q. Were there any other -- were there 13 any other people present, other than yourself, 14 Mr. Rannazzisi, Ms. Sannerud and counsel for 15 DOJ present during those discussions? 16 MR. CHANDLER: Objection. 17 Mischaracterizes prior testimony. 18 THE WITNESS: Mr. Rannazzisi and I 19 were not in the same room so I don't know who 20 was on the other end of the phone with him. 21 BY MR. EPPICH: 22 Q. Was there someone else on the phone 23 with him? 24 A. I don't know. I can't answer what I 25 could not see.</p>	<p style="text-align: right;">Page 125</p> <p>1 A. No. 2 Q. Who would be the final approver in 3 this list? 4 A. Michelle Leonard. 5 Q. And so does the list -- does the way 6 your approval process works, Mr. Rannazzisi 7 would approve it, Mr. Ryan would then approve 8 it, Mr. Mullinax -- or Ms. Mullinax would 9 approve it, Mr. Tuggle would then approve it 10 and then Ms. Leonard would approve it? Is that 11 -- is that how it works? 12 A. Yes. 13 Q. And is that process the same for 14 each -- each of these tables that you prepared 15 for us for each of the years in Exhibit No. 4? 16 MR. CHANDLER: Objection. 17 THE WITNESS: It does not seem to be 18 in that same order on all of these. 19 BY MR. EPPICH: 20 Q. Okay. For 2011, we are looking at 21 2011 in particular, Mr. Rannazzisi would have 22 approved the aggregate production quota amounts 23 for each of the classes in 2011, correct? 24 MR. ELSNER: Objection. 25 THE WITNESS: Yes.</p>

<p style="text-align: right;">Page 126</p> <p>1 BY MR. EPPICH:</p> <p>2 Q. And the same is true for each year 3 that we see Mr. Rannazzisi's name in Exhibit 4; 4 is that correct?</p> <p>5 A. Yes.</p> <p>6 Q. Now, Mr. Rannazzisi joined the 7 office of diversion control before 2011, 8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. And he had a role in his approval or 11 authorization of the aggregate production quota 12 before 2011?</p> <p>13 A. Yes.</p> <p>14 Q. And that would be true for his 15 tenure as the deputy assistant administrator 16 for the office of diversion control, correct?</p> <p>17 A. Correct.</p> <p>18 MR. EPPICH: Let's take a short 19 break.</p> <p>20 THE VIDEOGRAPHER: We are going off 21 the record. This is the end of Media Unit No. 22 3. The time is 2:02.</p> <p>23 (A short recess was taken.)</p> <p>24 THE VIDEOGRAPHER: We are going back 25 on the record. This is the start of Media Unit</p>	<p style="text-align: right;">Page 128</p> <p>1 MR. CHANDLER: Objection.</p> <p>2 THE WITNESS: That in 2013, there 3 was a 25 percent buffer added to the APQ for 4 FDA-approved products.</p> <p>5 BY MR. EPPICH:</p> <p>6 Q. And what did he mention about that? 7 A. That there were meetings held 8 between DEA and the bulk manufacturers 9 regarding that issue.</p> <p>10 Q. Anything else?</p> <p>11 A. No. That was a point of 12 clarification for me.</p> <p>13 Q. Were there any other points of 14 clarification Mr. Rannazzisi made to you?</p> <p>15 A. For that? No.</p> <p>16 Q. For any other topic, ma'am.</p> <p>17 A. Yes.</p> <p>18 Q. What did he say?</p> <p>19 A. That it was a point of clarification 20 on the section's ability to speak to 21 registrants.</p> <p>22 Q. And what was discussed?</p> <p>23 A. The basis for that.</p> <p>24 Q. What is the basis that he mentioned?</p> <p>25 A. That there were former DEA personnel</p>
<p style="text-align: right;">Page 127</p> <p>1 No. 4. The time is 2:12.</p> <p>2 You may proceed, Counsel.</p> <p>3 BY MR. EPPICH:</p> <p>4 Q. Ms. Harper-Avilla, you testified 5 today as DEA's 30(b)(6) witness for almost 6 three hours.</p> <p>7 Has any of your testimony been 8 informed by your discussions with Mr. 9 Rannazzisi and Ms. Sannerud?</p> <p>10 MR. CHANDLER: Objection.</p> <p>11 MR. ELSNER: Objection.</p> <p>12 THE WITNESS: They have clarified 13 issues that I may have had in preparation, but 14 -- they clarified issues I had in preparation.</p> <p>15 BY MR. EPPICH:</p> <p>16 Q. And what issues were clarified, 17 ma'am?</p> <p>18 A. Whether certain documents existed 19 for me to review or not.</p> <p>20 Q. Which documents were those?</p> <p>21 A. Documents related to setting the 22 APQ.</p> <p>23 Q. And what information specifically 24 did you discuss with Mr. Rannazzisi that 25 clarified issues for you?</p>	<p style="text-align: right;">Page 129</p> <p>1 who called various sections that were not 2 related to the topic at hand.</p> <p>3 Q. I am not understanding that.</p> <p>4 A. There were former DEA personnel 5 hired by manufacturers who would call a section 6 in order to seek guidance or special favor that 7 was not that section's ability or place.</p> <p>8 Q. And which sections were those that 9 were called?</p> <p>10 A. It varied. It just was a matter of 11 the fact that it was not -- they didn't call to 12 do work for that section or with that section.</p> <p>13 Q. Did you discuss any other points of 14 clarification?</p> <p>15 A. Yes.</p> <p>16 Q. And what were those points?</p> <p>17 A. DEA's investigation of the necessary 18 -- the need to actually change the regulations.</p> <p>19 Q. Which regulations?</p> <p>20 A. The ones in the C.F.R. or quota.</p> <p>21 Q. The regulations for quota?</p> <p>22 A. Correct.</p> <p>23 Q. And what did he say about the DEA's 24 need to change the regulations for quota?</p> <p>25 MR. CHANDLER: Objection. Scope.</p>

<p style="text-align: right;">Page 130</p> <p>1 THE WITNESS: That the document had 2 not been completed under him. 3 BY MR. EPPICH: 4 Q. What is the document, ma'am? 5 A. The proposed document, the proposed 6 notice of proposed rule making had not occurred 7 under him. 8 Q. Why was that important to him? 9 MR. CHANDLER: Objection. 10 THE WITNESS: It was not. It was 11 just a point of clarification. 12 BY MR. EPPICH: 13 Q. And you are referring to the 2018 14 revision to the C.F.R.; is that correct? 15 MR. CHANDLER: Objection. Scope. 16 THE WITNESS: I think we were 17 talking about things that he noticed needed to 18 be changed within the C.F.R. 19 BY MR. EPPICH: 20 Q. Limited to the quota or other 21 sections of the C.F.R.? 22 A. Not limited to quota. 23 Q. What other sections of the C.F.R. 24 did Mr. Rannazzisi say should be changed? 25 A. We did not --</p>	<p style="text-align: right;">Page 132</p> <p>1 A. Yes. 2 Q. And what were those, ma'am? 3 A. In regard to pharmaceutical training 4 seminars not going on through 2012 through 5 2015, being replaced instead by the pharmacy 6 diversion awareness conferences. 7 Q. And what did you discuss on that 8 topic? 9 A. Why -- we discussed whether or not 10 -- why they both could not go on at the same 11 time for each year. 12 Q. And why is that? 13 A. He felt that they overlapped and 14 caused confusion and it would be better served 15 to the agency if pharmaceutical -- that the 16 pharmaceutical diversion awareness conference 17 occurred instead, pharmacy diversion 18 conference. 19 Q. Were there any other points of 20 discussion or clarification that you discussed 21 with him in preparation for today's deposition? 22 A. Yes. 23 Q. What were those points? 24 A. The change in signature authority on 25 the individual quota letters.</p>
<p style="text-align: right;">Page 131</p> <p>1 MR. CHANDLER: Objection. Scope. 2 MR. ELSNER: Objection. 3 THE WITNESS: We didn't talk about 4 it that much because it was not relevant to my 5 preparation here. 6 BY MR. EPPICH: 7 Q. Did he mention any section at all? 8 MR. CHANDLER: Objection. Scope. 9 MR. ELSNER: Objection. 10 THE WITNESS: Just that he wanted to 11 make other changes. 12 BY MR. EPPICH: 13 Q. But he did not mention a specific 14 section that he wanted to change? 15 MR. CHANDLER: Objection. Scope. 16 MR. ELSNER: Objection. 17 THE WITNESS: He mentioned the fact 18 that in the course of making changes for the 19 quota, that there were other pieces that he had 20 not gotten to. 21 BY MR. EPPICH: 22 Q. Were there any other points of 23 clarification that you discussed with Mr. 24 Rannazzisi in preparation for today's 25 deposition?</p>	<p style="text-align: right;">Page 133</p> <p>1 Q. And what did -- what did you 2 discuss? 3 A. Clarification on the change that 4 occurred. 5 Q. What was the change that occurred? 6 A. That quota letters went from being 7 signed by the section chief to Mr. Rannazzisi. 8 Q. And when did that occur? 9 A. 2011. 10 Q. And these letters would be sent from 11 the DEA to who? 12 A. Individual manufacturers. 13 Q. And was there an issue with the 14 change in signatory? 15 MR. ELSNER: Objection. 16 MR. CHANDLER: Objection. 17 THE WITNESS: Not an issue with it. 18 Just a time and make sure I am clear on the 19 timing of when it occurred. 20 BY MR. EPPICH: 21 Q. And why would that be important? 22 MR. CHANDLER: Objection. 23 THE WITNESS: It was something that 24 I did not know at the time. I did not recall 25 correctly.</p>

<p style="text-align: right;">Page 134</p> <p>1 BY MR. EPPICH:</p> <p>2 Q. Were there any other points of 3 clarification that you discussed with Mr. 4 Rannazzisi during preparation sessions?</p> <p>5 A. Not that I can recall at this time.</p> <p>6 Q. Were there any points of 7 clarification that you discussed with Ms. 8 Sannerud?</p> <p>9 A. Yes.</p> <p>10 Q. And will you please explain those 11 points to us?</p> <p>12 MR. ELSNER: Objection.</p> <p>13 THE WITNESS: It was the signature 14 authority on the individual quota letters.</p> <p>15 BY MR. EPPICH:</p> <p>16 Q. Any other points of clarification?</p> <p>17 A. And again, also the 25 percent 18 increase put on to the APQ in 2013.</p> <p>19 Q. And what did Ms. Sannerud say about 20 the 25 percent increase put on to the APQ in 21 2013?</p> <p>22 A. That she remembered that it went to 23 only Schedule II substances.</p> <p>24 Q. Anything else?</p> <p>25 A. Just the time frame. That was it.</p>	<p style="text-align: right;">Page 136</p> <p>1 a short break.</p> <p>2 THE VIDEOGRAPHER: We are going off 3 the record. The time is 2:24.</p> <p>4 (A short recess was taken.)</p> <p>5 THE VIDEOGRAPHER: We are back on 6 the record. The time is 2:37.</p> <p>7 You may proceed, Counsel.</p> <p>8 MR. EPPICH: Thank you for your time 9 this afternoon, Ms. Harper-Avilla. We will 10 reserve -- we will pass the witness and reserve 11 our time for after your testimony.</p> <p>12 EXAMINATION BY COUNSEL FOR PLAINTIFFS 13 BY MR. ELSNER:</p> <p>14 Q. Good afternoon.</p> <p>15 A. Good afternoon.</p> <p>16 Q. My name is Mike Elsner, I'm from the 17 law firm Motley Rice and I represent the 18 plaintiffs.</p> <p>19 Does the Controlled Substances Act 20 create a closed system for manufacturing, 21 distributing and dispensing of controlled 22 substances?</p> <p>23 MR. CHANDLER: Objection. Scope.</p> <p>24 THE WITNESS: It is supposed to do 25 that.</p>
<p style="text-align: right;">Page 135</p> <p>1 Q. Did you discuss any other points of 2 clarification with Ms. Sannerud in preparation 3 for today's deposition?</p> <p>4 A. Also the ability of the section to 5 speak to registrants.</p> <p>6 Q. And what did you discuss in that 7 capacity?</p> <p>8 A. Whether or not she could remember 9 the time frame that it occurred in.</p> <p>10 Q. Was MS. Sannerud present for the 11 phone call with Mr. Rannazzisi?</p> <p>12 A. No, she was not.</p> <p>13 Q. These were separate phone calls?</p> <p>14 A. Correct.</p> <p>15 Q. Do you recall any other points of 16 clarifications or topics that you discussed 17 with Mr. Rannazzisi or Ms. Sannerud in 18 preparation for today's deposition?</p> <p>19 A. Not that I remember at this time, 20 no.</p> <p>21 Q. Did you discuss -- in your 22 preparations for today's deposition, did you 23 meet with any other members of the DEA?</p> <p>24 A. Not that I recall.</p> <p>25 MR. EPPICH: Let's go ahead and take</p>	<p style="text-align: right;">Page 137</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. And the DEA quota system is one 3 element within that closed system, but it's not 4 the only element; is that right?</p> <p>5 A. Correct.</p> <p>6 MR. CHANDLER: Objection. Scope.</p> <p>7 BY MR. ELSNER:</p> <p>8 Q. And do manufacturers and 9 distributors of controlled substances like 10 opioids have a responsibility to design a 11 system to monitor and detect suspicious orders?</p> <p>12 MR. CHANDLER: Objection. Scope.</p> <p>13 MR. O'CONNOR: Objection.</p> <p>14 THE WITNESS: Yes.</p> <p>15 BY MR. ELSNER:</p> <p>16 Q. And when suspicious orders are 17 detected, do manufacturers and distributors 18 have a duty to stop shipments of those orders 19 and report those orders to the DEA?</p> <p>20 MR. O'CONNOR: Objection. Scope.</p> <p>21 MR. CHANDLER: I'm going to direct 22 the witness not to answer, this is way outside 23 the scope.</p> <p>24 MR. ELSNER: I will tie it together 25 quickly. I just want to give her a basic</p>

<p style="text-align: right;">Page 138</p> <p>1 overview.</p> <p>2 MR. CHANDLER: Can you explain, tied 3 together on what basis? How does this tie 4 together?</p> <p>5 MR. ELSNER: You will see in the -- 6 within the next few exhibits, I will show you. 7 There's certain statements made by counsel in 8 relationship to their responsibilities that 9 don't exist because there is a quota system in 10 place.</p> <p>11 MR. CHANDLER: Are these questions 12 really necessary to get there?</p> <p>13 MR. ELSNER: I think it sets the 14 stage for that, yes.</p> <p>15 MR. O'CONNOR: Defendants object.</p> <p>16 MR. CHANDLER: You can answer. 17 Do you need the question again?</p> <p>18 THE WITNESS: I need the question 19 again.</p> <p>20 BY MR. ELSNER:</p> <p>21 Q. Sure. When suspicious orders are 22 detected, do manufacturers and distributors 23 have a duty to stop shipments of those orders 24 and report those suspicious orders to the DEA?</p> <p>25 MR. O'CONNOR: Objection. Form.</p>	<p style="text-align: right;">Page 140</p> <p>1 one portion of it, but it's incumbent upon the 2 manufacturers and distributors and all of the 3 participants within the quota system, within 4 the controlled substance system, to do their 5 part as per the regulations.</p> <p>6 BY MR. ELSNER:</p> <p>7 Q. Okay. So simply because there is a 8 quota system in place, that doesn't excuse 9 manufacturers and distributors from fulfilling 10 their other obligations under the Controlled 11 Substances Act; is that right?</p> <p>12 MR. CHANDLER: Objection. Scope.</p> <p>13 MR. O'CONNOR: Objection.</p> <p>14 THE WITNESS: True.</p> <p>15 MR. ELSNER: I want to mark Exhibit 16 9. This is a transcript. (Deposition Exhibit 9 was marked for 17 identification.)</p> <p>18 BY MR. ELSNER:</p> <p>19 Q. This is a transcript of a hearing in 20 federal court in West Virginia and I want you 21 to turn to Page 12 of the transcript and I want 22 to review certain statements made in this 23 transcript and see if you agree or disagree 24 with them. Okay?</p>
<p style="text-align: right;">Page 139</p> <p>1 MR. CHANDLER: Objection. Scope. 2 You can answer.</p> <p>3 THE WITNESS: I can't answer your 4 question fully because that's not quite my area 5 of expertise.</p> <p>6 They definitely have a requirement 7 to notify DEA.</p> <p>8 BY MR. ELSNER:</p> <p>9 Q. Okay. And you mentioned among the 10 other factors that the DEA may consider is 11 known diversion.</p> <p>12 What did you mean by "known?"</p> <p>13 A. Known would be something that had 14 been adjudicated through the process.</p> <p>15 Q. Is the responsibility for 16 manufacturers and distributors to monitor for 17 suspicious orders, stopping shipments of 18 suspicious orders and inform the DEA, does that 19 responsibility go away because there is a quota 20 system in place by the DEA?</p> <p>21 MR. O'CONNOR: Object to form and 22 scope.</p> <p>23 MR. CHANDLER: Objection. Scope.</p> <p>24 MR. EPPICH: Objection. Foundation.</p> <p>25 THE WITNESS: So the quota system is</p>	<p style="text-align: right;">Page 141</p> <p>1 Are you on Page 12?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. At the very top of the page, 4 it says: "We, the distributors, Your Honor, 5 have absolutely no role in determining what the 6 supply needs to be or in making a determination 7 of what the demand is."</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. And then if you go down, it 11 says, after the dashes: "But the DEA every 12 year sets the quota in this country for all 13 Schedule I and Schedule II controlled 14 substances that may be manufactured by the 15 manufacturers and it sets that quota based on 16 its evaluation of legitimate medical, 17 scientific, industrial need for those 18 substances."</p> <p>19 Did I read that correctly?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. The Court asks: "Is that a 22 nationwide or is it a state specific? How is 23 it broken down?"</p> <p>24 Counsel for the distributors 25 responds: "It's nationwide, Your Honor."</p>

<p style="text-align: right;">Page 142</p> <p>1 The Court then asks -- if you are 2 with me under where the Court -- it says: 3 "Does that overcome the obligation of the 4 distributors to be on the lookout for 5 suspicious high numbers of drugs going into 6 specific areas?" 7 And the distributors lawyer says: 8 "It does." 9 Is that statement accurate or 10 inaccurate? 11 MR. EPPICH: Objection. Foundation. 12 Form. Outside the scope. 13 MR. CHANDLER: Objection. 14 MR. O'CONNOR: Objection. 15 THE WITNESS: I'm not sure what the 16 Court's question refers to at this point. I 17 apologize. 18 BY MR. ELSNER: 19 Q. That's okay. The Court is asking 20 whether that obviates the distributors need to 21 be on the lookout for suspicious high numbers 22 of drugs going into specific areas, and the 23 distributors lawyer says that it does. 24 That statement is not true; is that 25 right?</p>	<p style="text-align: right;">Page 144</p> <p>1 Controlled Substances Act is a fair inquiry. 2 MR. CHANDLER: Well, she is not 3 going to testify or designated to testify about 4 the establishment of quotas and the quota 5 setting process, not other impacts it may have 6 on other obligations of distributors or 7 registrants. 8 MR. ELSNER: I think she is entitled 9 to answer this question. She already answered 10 the question essentially. 11 MR. O'CONNOR: The Touhy 12 authorization is pretty limited in terms of the 13 policies around the quota process and certain 14 other topics that don't include obligations 15 when there's suspicious monitoring. 16 MR. EPPICH: The distributors would 17 also agree that this is well beyond the scope 18 of the 30(b)(6) topics and any testimony that 19 she may or may not provide would be personal 20 testimony and no foundation has been 21 established for any such testimony. 22 MR. RUIZ: The pharmacies would 23 agree as well. 24 MR. CHANDLER: Yeah, I mean, Topic 3 25 is establishment of quotas for production of</p>
<p style="text-align: right;">Page 143</p> <p>1 MR. EPPICH: Objection. Foundation. 2 Form. Scope. 3 MR. O'CONNOR: Objection. Scope. 4 MR. CHANDLER: This is well outside 5 Topics 13 and 14 and outside the Touhy 6 authorization. 7 Is this the big tie together that 8 you promised a moment ago? 9 MR. ELSNER: I don't -- it is. I 10 don't think that it is beyond the scope. The 11 distributors have taken the responsibility 12 before federal court that they are -- they are 13 not obligated to fulfill their responsibilities 14 because there is a quota system in place, and I 15 want to make sure that that is inconsistent 16 with the DEA's view of their responsibilities 17 under the quota system. 18 MR. CHANDLER: Ms. Harper-Avilla has 19 not been designated to testify about 20 distributors' obligations related to reporting 21 before the Court. 22 MR. ELSNER: No, I understand that, 23 but she is responsible for the quota system and 24 I think she's -- and I think whether that 25 obviates the other responsibilities under the</p>	<p style="text-align: right;">Page 145</p> <p>1 opioids in the United States, not secondary 2 impacts or other obligations of registrants as 3 a result of quotas. 4 MR. ELSNER: I understand. I think 5 if I get an answer to this question, we can 6 move on. I'm not going to belabor this. 7 MR. CHANDLER: This is the last 8 question on this topic? 9 MR. ELSNER: Yes. 10 MR. CHANDLER: All right. 11 MR. EPPICH: We can still make our 12 objection. 13 MR. CHANDLER: Our scope objection 14 stands. I will allow the witness to answer in 15 her personal capacity, not on behalf of the 16 DEA. 17 You can answer if you know. 18 THE WITNESS: Can I have the 19 question again? 20 BY MR. ELSNER: 21 Q. You may. The simple question is, is 22 -- the Court asked counsel whether -- in the 23 transcript, as a federal district court judge, 24 whether the quota system overcame the 25 obligations of the distributors to be on the</p>

<p style="text-align: right;">Page 146</p> <p>1 lookout for suspicious high numbers of drugs 2 going into specific areas, and counsel for the 3 distributors said, it did. It overcame that 4 responsibility.</p> <p>5 And my question to you is: In your 6 personal capacity, is that consistent or 7 inconsistent with your understanding of the 8 Controlled Substances Act?</p> <p>9 MR. CHANDLER: I will renew my 10 objection.</p> <p>11 MR. O'CONNOR: Objection. Scope. 12 MR. EPPICH: Same objection. In 13 addition to any -- to the extent it 14 mischaracterizes the testimony on this 15 document.</p> <p>16 MS. McCLURE: Object to this line of 17 questioning and the characterization of 18 distributors and treating this argument as on 19 behalf of the distributors as a whole.</p> <p>20 MR. CHANDLER: You can answer if you 21 know.</p> <p>22 THE WITNESS: The quota system does 23 not change the obligation of the distributors 24 under this CSA.</p> <p>25 BY MR. ELSNER:</p>	<p style="text-align: right;">Page 148</p> <p>1 be made. 2 BY MR. ELSNER: 3 Q. Okay. So can the DEA tell Purdue 4 you cannot manufacture an 80 milligram 5 OxyContin pill under the quota system? 6 MR. MASTERS: Objection. 7 MR. CHANDLER: Objection. 8 THE WITNESS: The DEA would be able 9 to limit them only if it was not FDA-approved. 10 BY MR. ELSNER: 11 Q. Okay. But otherwise, they can -- 12 but in any case, they cannot approve or 13 disapprove of a particular dose of the use of 14 the bulk substance, correct? 15 MR. CHANDLER: Objection. 16 MR. O'CONNOR: Object to form. 17 THE WITNESS: Correct. 18 BY MR. ELSNER: 19 Q. Would you agree with me that there 20 are some types of drugs that are more abused 21 than other drugs? 22 MR. CHANDLER: Objection. Scope. 23 MR. O'CONNOR: Objection. 24 MR. EPPICH: Objection. Vague. 25 THE WITNESS: I would not have a</p>
<p style="text-align: right;">Page 147</p> <p>1 Q. Thank you. I want to turn to 2 procurement quotas for a second, and in the 3 procurement quota process, does the DEA approve 4 in the quota system the dose of an opioid 5 product that a manufacturer may make?</p> <p>6 A. No.</p> <p>7 MR. O'CONNOR: Objection to form. 8 BY MR. ELSNER: 9 Q. The DEA is really just authorizing a 10 gross bulk amount of a controlled substance 11 that a manufacturer may acquire to create a 12 dose; is that right?</p> <p>13 MR. O'CONNOR: Objection to form. 14 THE WITNESS: Correct. 15 BY MR. ELSNER: 16 Q. Okay. The DEA cannot issue a quota 17 or a limit on the dosage units or number of 18 specific opioid pills that a manufacturer can 19 make, can they?</p> <p>20 MR. MASTERS: Objection. 21 MR. CHANDLER: Objection. 22 THE WITNESS: The quota that is 23 granted is by weight, kilogram, and in the 24 sense, it will limit it that way, but it does 25 not specific -- specify X number of tablets to</p>	<p style="text-align: right;">Page 149</p> <p>1 basis for that. 2 BY MR. ELSNER: 3 Q. Are you aware just in your personal 4 capacity whether a red flag for diversion could 5 be when a patient refers to an oxycodone pill 6 as a blue or a panda bear or an octagon? 7 MS. McCLURE: Objection to form. 8 MR. EPPICH: Objection to form. 9 MR. O'CONNOR: Objection to form. 10 Scope. 11 MR. CHANDLER: Objection to form. 12 Scope. 13 THE WITNESS: I would think that 14 that means that it's not for the intended 15 purpose. 16 BY MR. ELSNER: 17 Q. Okay. And we all understand that 18 there are certain drugs that are more subject 19 to abuse than other drugs, but can the DEA 20 through the quota system focus on creating a 21 limit on the specific type of drug that is most 22 subject to abuse? 23 MR. O'CONNOR: Object to form. 24 MR. CHANDLER: Objection. Scope. 25 MR. EPPICH: Objection. Foundation.</p>

<p style="text-align: right;">Page 150</p> <p>1 THE WITNESS: I don't understand 2 your question. I'm sorry. 3 BY MR. ELSNER: 4 Q. That's okay. My question is, is 5 whether the DEA in the quota system could limit 6 the authorization and just restrict 7 authorization to the drugs that are most 8 subject to abuse?</p> <p>9 MR. CHANDLER: Objection. Scope. 10 MR. O'CONNOR: Objection. 11 THE WITNESS: Within the quota 12 system, if it's an FDA-approved product without 13 actual case data, then it would not be limited. 14 BY MR. ELSNER: 15 Q. Because what the DEA is looking at 16 is the gross -- is the gross bulk amount of the 17 substance, right? 18 They are not looking at the specific 19 type of medicine or the specific dose, correct? 20 MR. O'CONNOR: Objection. Form. 21 MS. MCCLURE: Objection. Form. 22 Vague. Compound. 23 THE WITNESS: The DEA looks at bulk 24 data. 25 BY MR. ELSNER:</p>	<p style="text-align: right;">Page 152</p> <p>1 BY MR. ELSNER: 2 Q. And the DEA, through the quota 3 system, it doesn't analyze and approve 4 individual orders from pharmacies, to 5 manufacturers or to wholesale distributors, 6 does it? 7 A. It does not. 8 Q. Okay. And the quota system doesn't 9 authorize the number of pills that could be 10 distributed into Summit County or Cabell County 11 in West Virginia, does it? 12 MR. CHANDLER: Object to form. 13 MR. O'CONNOR: Object to form. 14 THE WITNESS: It does not. 15 BY MR. ELSNER: 16 Q. And it doesn't authorize the number 17 of pills that a distributor could send to any 18 city or county in the United States, does it? 19 A. It does not. It is national. It is 20 not county, not city, not state-specific. 21 Q. Okay. So the DEA is really just 22 approving a gross bulk amount of a controlled 23 substance that a manufacturer can acquire to 24 produce certain drugs that could be then made 25 into any type of drug at any dose and sold into</p>
<p style="text-align: right;">Page 151</p> <p>1 Q. Okay. The quota system run by the 2 DEA is also national in scope; is that right? 3 A. Correct. 4 Q. Okay. It didn't -- it doesn't look 5 at -- the quota system for the DEA doesn't look 6 at how many pills a distributor like 7 AmerisourceBergen or Cardinal could distribute 8 to a particular pharmacy in a particular 9 community, does it? 10 MR. CHANDLER: Objection. Scope. 11 MR. MASTERS: Objection. 12 THE WITNESS: It does not. 13 BY MR. ELSNER: 14 Q. Okay. And the quota system, even if 15 you reduce the quota, it couldn't prevent a 16 distributor like McKesson from distributing 17 112,000 doses units of Hydrocodone products 18 into one pharmacy in West Virginia with a 19 population of 1500 people, could it? 20 MR. CHANDLER: Object to form. 21 MR. O'CONNOR: Objection. Scope. 22 MR. EPPICH: Objection. 23 THE WITNESS: The quota system is 24 national so it has no control over distributor 25 contracts.</p>	<p style="text-align: right;">Page 153</p> <p>1 any town into America; is that right? 2 MS. MCCLURE: Object to form. 3 MR. EPPICH: Objection. Vague. 4 MR. O'CONNOR: Objection to form. 5 MR. CHANDLER: Object to form. 6 THE WITNESS: Quota is granted for 7 any FDA-approved product to be distributed into 8 the patient population. 9 BY MR. ELSNER: 10 Q. Without respect to the particular 11 location of national scope, correct? 12 A. It is national in scope. 13 Q. Now, correct me if I am wrong, but 14 it's the manufacturer that requests 15 authorization to purchase a bulk amount of a 16 certain drug; is that right? 17 MR. O'CONNOR: Objection to form. 18 THE WITNESS: Correct. 19 BY MR. ELSNER: 20 Q. Okay. And at any time a 21 manufacturer could say, I no longer want 22 authorization to purchase these controlled 23 substances, right? 24 MR. O'CONNOR: Objection to form. 25 THE WITNESS: Correct.</p>

<p style="text-align: right;">Page 154</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. It's not the U.S. -- the U.S.</p> <p>3 Government cannot make a manufacturer seek an</p> <p>4 authorization to purchase bulk controlled</p> <p>5 drugs, right?</p> <p>6 A. Correct.</p> <p>7 Q. In fact, DEA, through the quota</p> <p>8 system, cannot make a manufacturer seek a</p> <p>9 specific authorization for a specific type of</p> <p>10 drug either, can it?</p> <p>11 A. I don't understand the question.</p> <p>12 Q. The DEA -- can the DEA instruct a</p> <p>13 manufacturer to seek an authorization for a</p> <p>14 specific type of controlled substance to make a</p> <p>15 particular product?</p> <p>16 A. No, it cannot.</p> <p>17 Q. And the DEA cannot require</p> <p>18 manufacturers or distributors to distribute</p> <p>19 controlled substance down through the supply</p> <p>20 chain, can it?</p> <p>21 MR. MASTERS: Objection. Scope.</p> <p>22 MR. EPPICH: Objection. Foundation.</p> <p>23 THE WITNESS: No.</p> <p>24 BY MR. ELSNER:</p> <p>25 Q. Just because a manufacturer may be</p>	<p style="text-align: right;">Page 156</p> <p>1 MR. CHANDLER: Object to form.</p> <p>2 MR. EPPICH: Object to form.</p> <p>3 THE WITNESS: Based on the</p> <p>4 application that the manufacturer submitted, it</p> <p>5 could -- they did not -- they do not need to</p> <p>6 use it for that year, but they should use it in</p> <p>7 the second year as an inventory allowance.</p> <p>8 BY MR. ELSNER:</p> <p>9 Q. The statute says that the DEA was to</p> <p>10 establish the total annual needs of controlled</p> <p>11 substances in the United States to provide for</p> <p>12 the estimated medical, scientific research and</p> <p>13 industrial needs in the U.S.; is that right?</p> <p>14 A. And inventory allowance and export</p> <p>15 included.</p> <p>16 Q. And one of the factors that the DEA</p> <p>17 must consider when establishing the quota is</p> <p>18 whether there is an adequate supply of a given</p> <p>19 drug; is that right?</p> <p>20 A. Correct.</p> <p>21 Q. And, in fact, the DEA must ensure</p> <p>22 that there is both an adequate and an</p> <p>23 uninterrupted supply of those controlled</p> <p>24 substances available for legitimate medical use</p> <p>25 and other things, correct?</p>
<p style="text-align: right;">Page 155</p> <p>1 able to obtain an authorization for an opioid,</p> <p>2 that doesn't mean a manufacturer needs to</p> <p>3 actually purchase the opioids, right?</p> <p>4 MR. MASTERS: Objection. Scope.</p> <p>5 MR. EPPICH: Objection. Foundation.</p> <p>6 MR. CHANDLER: Objection.</p> <p>7 THE WITNESS: Correct.</p> <p>8 BY MR. ELSNER:</p> <p>9 Q. And once a quota is issued, it can</p> <p>10 be increased or decreased throughout the year;</p> <p>11 is that true?</p> <p>12 A. At the request of the manufacturer</p> <p>13 itself.</p> <p>14 Q. Can the DEA request the manufacturer</p> <p>15 to decrease or increase the quota?</p> <p>16 A. No.</p> <p>17 Q. And if a manufacturer receives an</p> <p>18 authorization for a quota and purchases the</p> <p>19 bulk amount of that drug, that doesn't mean</p> <p>20 they need to use all of that drug in a given</p> <p>21 year to manufacture pills. They could spread</p> <p>22 it over several years if they informed the DEA;</p> <p>23 is that true?</p> <p>24 MS. McCLURE: Object to form.</p> <p>25 Compound. Vague.</p>	<p style="text-align: right;">Page 157</p> <p>1 A. Correct.</p> <p>2 Q. It is also true, isn't it, that</p> <p>3 under the Food & Drug Administration Safety</p> <p>4 Innovation Act, that the FDA could request that</p> <p>5 the DEA increase quotas applicable to a</p> <p>6 particular substance if the FDA determines</p> <p>7 that's necessary; is that true?</p> <p>8 MR. EPPICH: Objection. Vague.</p> <p>9 THE WITNESS: Can I have that asked</p> <p>10 again, please.</p> <p>11 BY MR. ELSNER:</p> <p>12 Q. If the FDA is notified of a supply</p> <p>13 disruption of certain drugs that contain</p> <p>14 controlled substances subject to a quota, the</p> <p>15 FDA, under the Food & Drug Administration</p> <p>16 Safety Innovation Act, requires that the FDA</p> <p>17 request DEA to increase the quota applicable to</p> <p>18 that controlled substance if the FDA determines</p> <p>19 it's necessary; is that true?</p> <p>20 MR. EPPICH: Objection.</p> <p>21 MR. O'CONNOR: Objection.</p> <p>22 MR. CHANDLER: Objection.</p> <p>23 THE WITNESS: It requires that the</p> <p>24 FDA and DEA enter into a dialogue in order to</p> <p>25 determine whether it's necessary or not to</p>

<p style="text-align: right;">Page 158</p> <p>1 increase the quota. 2 MR. ELSNER: I will mark this as 3 Exhibit 10. 4 (Deposition Exhibit 10 was marked 5 for identification.) 6 BY MR. ELSNER: 7 Q. This is a DEA PowerPoint 8 presentation and it's from a presentation done 9 in New Orleans, and it's the 11th 10 Pharmaceutical Industry Conference. 11 There is not a year on the beginning 12 of the document but we have been able to 13 determine that that conference occurred in 14 2003. Okay? 15 A. Okay. 16 Q. I'm going to ask you to turn to Page 17 10 of the presentation. There is a slide there 18 that reads: "Quota factors." 19 The second bullet there, it reads: 20 "There is no real means of determining 21 legitimate medical need for product substance 22 class." 23 And then it says underneath that: 24 "Because we are treating symptoms, pain, 25 insomnia and the like."</p>	<p style="text-align: right;">Page 160</p> <p>1 THE WITNESS: Correct. 2 BY MR. ELSNER: 3 Q. And the third bullet there says 4 there's no federal regulation of the practice 5 of medicine and so the DEA cannot regulate the 6 practice of medicine; is that true? 7 MR. CHANDLER: Objection. Scope. 8 THE WITNESS: I'm not sure of your 9 question. 10 BY MR. ELSNER: 11 Q. Well, my question was just whether 12 you agreed with that bullet, that the DEA 13 cannot regulate the practice of medicine, 14 certainly not through the quota system, 15 correct? 16 MR. CHANDLER: Objection. Scope. 17 Vague. 18 MR. MASTERS: Counsel, is there a 19 Bates number for this document? 20 MR. ELSNER: It's on the last page. 21 MS. MCCLURE: For purposes of the 22 record, it is Bates 03000179742, TPLCP 23 03000179742. 24 THE WITNESS: So DEA will regulate 25 only as far as a doctor who writes a</p>
<p style="text-align: right;">Page 159</p> <p>1 Do you agree with that bullet point 2 from the DEA presentation that there is no real 3 means of determining legitimate medical need 4 for a product? 5 MR. O'CONNOR: Objection. 6 THE WITNESS: That is the FDA's role 7 in all of this so DEA cannot respond to that. 8 BY MR. ELSNER: 9 Q. But just in terms of practical 10 sense, the role of the DEA is to establish an 11 estimate of medical need. You could never 12 determine the exact precise medical need at any 13 given point in time; is that fair? 14 MR. CHANDLER: Objection. Form. 15 MS. MCCLURE: Objection. Form. 16 Vague. 17 THE WITNESS: Correct. 18 BY MR. ELSNER: 19 Q. So you rely on a bunch of different 20 factors to consider that, but at the end of the 21 day, it's an estimate because you can never be 22 exactly precise; is that true? 23 MS. MCCLURE: Objection. 24 MR. O'CONNOR: Objection. 25 MR. CHANDLER: Object to form.</p>	<p style="text-align: right;">Page 161</p> <p>1 prescription for a controlled substance needs 2 to be registered with the DEA. 3 BY MR. ELSNER: 4 Q. Okay. Because there is no precise 5 means of determining the exact medical need, 6 one of the factors that the DEA considers are 7 data that is provided by the manufacturers such 8 as sales data, correct? 9 MR. O'CONNOR: Objection. Form. 10 THE WITNESS: Correct. 11 MS. NEWMARK: Counsel, I'm going to 12 object to the use of this document, the Purdue 13 document that was produced pursuant to the 14 protective order in this case. If you would -- 15 you haven't established a foundation for what 16 this document -- where it came from. 17 MR. ELSNER: Well, it's a DEA 18 document. 19 MS. NEWMARK: Did you seek 20 permission to use it from Purdue? 21 MR. ELSNER: I don't need to seek 22 permission to use a DEA document from Purdue. 23 MS. NEWMARK: Well, you haven't -- 24 it is marked confidential. You have not 25 established that this is a DEA document.</p>

<p style="text-align: right;">Page 162</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. Ma'am, is there a DEA logo on the 3 front page of the document?</p> <p>4 A. Yes.</p> <p>5 Q. Does it read DEA OD 11th 6 Pharmaceutical Industry Conference?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Isn't it true that individual 9 quotas for each registrant are calculated based 10 on the business activities and justification 11 they provide to the DEA?</p> <p>12 MR. O'CONNOR: Objection. Form.</p> <p>13 THE WITNESS: It's based on their 14 business activities and a part of it on their 15 justification, yeah.</p> <p>16 BY MR. ELSNER:</p> <p>17 Q. Okay. And you'd agree that the 18 quality of the data -- that the quality of the 19 quota calculation is based on the quality of 20 the data provided in part by the manufacturers. 21 Would you agree with that?</p> <p>22 MR. O'CONNOR: Objection. Form.</p> <p>23 MR. EPPICH: Objection. Vague.</p> <p>24 THE WITNESS: Part of that data is 25 the consideration, yes.</p>	<p style="text-align: right;">Page 164</p> <p>1 data as reported by the manufacturers, does the 2 DEA have the ability to actually look in 3 realtime behind the sales data that is 4 provided?</p> <p>5 MR. O'CONNOR: Objection to form.</p> <p>6 THE WITNESS: No.</p> <p>7 BY MR. ELSNER:</p> <p>8 Q. And so, in part, you are relying on 9 -- although you are skeptical, you are relying 10 on the information that the manufacturers 11 provide to you in order to assess legitimate 12 medical need in part, correct?</p> <p>13 MR. CHANDLER: Objection. Form.</p> <p>14 MR. O'CONNOR: Objection. Form.</p> <p>15 MR. EPPICH: Objection. Form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 MR. ELSNER: This is Exhibit 11. (Deposition Exhibit 11 was marked 18 for identification.)</p> <p>19 BY MR. ELSNER:</p> <p>20 Q. I'm going to ask you to -- it's a 21 collection of e-mails. I'm going to ask you to 22 turn to the very last page of the document. 23 This is an e-mail from Richard 24 Sackler of Purdue.</p>
<p style="text-align: right;">Page 163</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. Okay. And there would be an 3 expectation that the data that would be 4 provided would be both accurate and complete, 5 right?</p> <p>6 MR. EPPICH: Object to form. Vague.</p> <p>7 THE WITNESS: So DEA was -- is 8 skeptical of data submitted by the 9 manufacturers and therefore relies on the 10 third-party prescription data as well.</p> <p>11 BY MR. ELSNER:</p> <p>12 Q. For sure. And we will get to the 13 prescription data.</p> <p>14 Why is the DEA skeptical of the data 15 provided by manufacturers?</p> <p>16 MR. O'CONNOR: Objection. Form.</p> <p>17 THE WITNESS: Because based on the 18 business activities, the manufacturers may not 19 fully state what is actually being -- what is 20 actually necessary for patient consumption.</p> <p>21 BY MR. ELSNER:</p> <p>22 Q. And when they do that, that could 23 impact the size of the quota, correct?</p> <p>24 A. Correct.</p> <p>25 Q. When the DEA is reviewing the sales</p>	<p style="text-align: right;">Page 165</p> <p>1 MS. NEWMARK: Objection to form.</p> <p>2 BY MR. ELSNER:</p> <p>3 Q. And he writes: "I think we should 4 move our allocation upward again. I believe 5 that we should be able to handle an increase up 6 to 175 million for this year in demand and well 7 above 200 million next year. Michael will give 8 you numbers today but I think this is close to 9 ballpark."</p> <p>10 Then he asks: "What is our 11 allocation for now? Am I right in estimating 12 that we are earning about \$60,000 per kilogram 13 sold. If so, it would appear that we need 14 about 2,925 kilograms of oxycodone HCL for this 15 year and something approaching 4,000 kilograms 16 next year."</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 MR. O'CONNOR: Object to form.</p> <p>20 MS. NEWMARK: Object to form, and 21 I'm going to object to the use of this e-mail.</p> <p>22 Once again, this is a Purdue document that was 23 produced pursuant to a confidentiality order.</p> <p>24 There is no indication that -- yet again, that 25 counsel sought permission to use this e-mail</p>

<p style="text-align: right;">Page 166</p> <p>1 and it's outside the scope of the permit.</p> <p>2 BY MR. ELSNER:</p> <p>3 Q. Did DEA know that Purdue had</p> <p>4 internal estimates that they could earn \$60,000</p> <p>5 for every kilogram of oxycodone authorized?</p> <p>6 MR. O'CONNOR: Objection to form and</p> <p>7 scope.</p> <p>8 MR. CHANDLER: Objection to scope</p> <p>9 and I will instruct witness not to answer.</p> <p>10 Specifically excluded from the deposition</p> <p>11 notice, any consideration of particular quota</p> <p>12 amounts for particular years for particular</p> <p>13 registrants.</p> <p>14 MR. ELSNER: My question -- my</p> <p>15 question is not to analyze whether the DEA</p> <p>16 considered any specific quota requests from any</p> <p>17 manufacturer.</p> <p>18 My question is simply whether the</p> <p>19 DEA was aware that certain manufacturers were</p> <p>20 calculating quota based on the dollars they</p> <p>21 could earn off the kilograms authorized.</p> <p>22 That's my question.</p> <p>23 MR. O'CONNOR: Objection.</p> <p>24 MR. CHANDLER: With reference to</p> <p>25 this particular e-mail and those particular</p>	<p style="text-align: right;">Page 168</p> <p>1 legitimate medical need, it could offset an</p> <p>2 impact to the quota authorization, right?</p> <p>3 MR. O'CONNOR: Objection. Form.</p> <p>4 MR. CHANDLER: Objection. Vague.</p> <p>5 Form.</p> <p>6 THE WITNESS: I'm not -- I don't</p> <p>7 understand your question.</p> <p>8 BY MR. ELSNER:</p> <p>9 Q. Okay. If a manufacturer was seeking</p> <p>10 authorization of quota, not by determining</p> <p>11 actual medical data but instead by determining</p> <p>12 how much profit they could earn, that could</p> <p>13 offset the quota authorization, correct?</p> <p>14 MS. MCCLURE: Objection to form.</p> <p>15 Foundation. Vague. Compound.</p> <p>16 MR. CHANDLER: Objection. Form.</p> <p>17 MR. O'CONNOR: Objection.</p> <p>18 MS. MCCLURE: Calls for speculation.</p> <p>19 THE WITNESS: The DEA would seek a</p> <p>20 third-party data in terms of trying to</p> <p>21 determine actual legitimate medical need for</p> <p>22 that particular manufacturer.</p> <p>23 BY MR. ELSNER:</p> <p>24 Q. I understand that the DEA has other</p> <p>25 systems it could use. It looks at IMS data,</p>
<p style="text-align: right;">Page 167</p> <p>1 amounts, I'm going to instruct the witness not</p> <p>2 to answer that.</p> <p>3 BY MR. ELSNER:</p> <p>4 Q. Was the DEA aware, ma'am, that</p> <p>5 manufacturers of opioids were establishing</p> <p>6 quota based on the dollars they could earn off</p> <p>7 the quota authorized?</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 MS. NEWMARK: Object to form.</p> <p>10 Object to foundation.</p> <p>11 MR. CHANDLER: Object to form.</p> <p>12 THE WITNESS: The DEA was not aware.</p> <p>13 BY MR. ELSNER:</p> <p>14 Q. The quota authorization was supposed</p> <p>15 to be based on legitimate medical need,</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. It's not supposed to -- it's not</p> <p>19 supposed to be based on how much profit you can</p> <p>20 earn of the quota authorized, correct?</p> <p>21 MR. O'CONNOR: Objection.</p> <p>22 THE WITNESS: Correct.</p> <p>23 BY MR. ELSNER:</p> <p>24 Q. And if you calculate a quota based</p> <p>25 on how much you could earn instead of</p>	<p style="text-align: right;">Page 169</p> <p>1 prescription data, we're going to get there.</p> <p>2 But my question is is that if</p> <p>3 manufacturers were giving the DEA data and</p> <p>4 requesting quota authorizations based on the</p> <p>5 profit they could earn instead of legitimate</p> <p>6 medical need, that could impact the quota</p> <p>7 authorization?</p> <p>8 MR. CHANDLER: Objection.</p> <p>9 MS. MCCLURE: Same objection.</p> <p>10 MR. CHANDLER: Vague. Calls for</p> <p>11 speculation. Objection to form.</p> <p>12 THE WITNESS: If a manufacturer used</p> <p>13 that process, then they would probably</p> <p>14 overestimate the amount of quota.</p> <p>15 BY MR. ELSNER:</p> <p>16 Q. Just above the e-mail from Richard</p> <p>17 Sackler, there is an e-mail from James</p> <p>18 Sullivan, and at the end of the second</p> <p>19 paragraph, he says: "I'd asked for 1,1800-plus</p> <p>20 and I have been given 1,412. I will ask for a</p> <p>21 plus-700 and probably get 400, then go back</p> <p>22 again in the summer for more."</p> <p>23 MS. NEWMARK: Counsel, again, I'm</p> <p>24 objecting to the use of this e-mail. This</p> <p>25 e-mail was produced in a different litigation</p>

<p style="text-align: right;">Page 170</p> <p>1 pursuant to a confidentiality order and Mr. 2 Chandler already instructed the witness not to 3 answer subject to that.</p> <p>4 MR. MASTERS: And further, I would 5 add that pursuant to the DEA's authorization 6 letter, to the extent that these -- that this 7 e-mail reflects procurement quota applications, 8 it is outside the scope of the DEA 9 authorization which is not the decision with 10 respect to individual procurement quota for any 11 given year.</p> <p>12 BY MR. ELSNER:</p> <p>13 Q. My question is whether the DEA was 14 aware that manufacturers would sometimes ask 15 for more quota than they actually needed with 16 the hope that they would -- sorry, my question 17 is whether -- let me strike that.</p> <p>18 My question is whether DEA was aware 19 that manufacturers would sometimes ask for more 20 quota than they actually needed.</p> <p>21 MR. O'CONNOR: Objection to form.</p> <p>22 MR. CHANDLER: Objection. Scope.</p> <p>23 MS. McCLURE: Form. Speculation. 24 Foundation.</p> <p>25 MR. MASTERS: We object as well.</p>	<p style="text-align: right;">Page 172</p> <p>1 instruction as to whether this witness is 2 permitted to answer questions regarding 3 individual situations or not.</p> <p>4 MR. CHANDLER: You can answer the 5 question subject to my objection.</p> <p>6 THE WITNESS: If a manufacturer 7 suggested that their sales outpaced and that 8 they had used up their inventory, it would 9 result in probably a higher quota.</p> <p>10 MR. ELSNER: Mark this document as 11 Exhibit 12.</p> <p>12 (Deposition Exhibit 12 was marked 13 for identification.)</p> <p>14 MS. McCLURE: For the record, could 15 you please read the confidentiality designation 16 that may appear on the document as well as the 17 Bates numbers for the record as per the 18 deposition protocol.</p> <p>19 MR. ELSNER: I will give the Bates 20 numbers. P 2421610 through 1612.</p> <p>21 MS. NEWMARK: Object to the extent 22 this is in violation of the protective order in 23 this case and the information that appears in 24 the foot of the document is in a different 25 lawsuit.</p>
<p style="text-align: right;">Page 171</p> <p>1 MR. CHANDLER: You can answer.</p> <p>2 THE WITNESS: DEA was aware that 3 manufacturers asked for larger quotas than was 4 supported by actual documentation.</p> <p>5 BY MR. ELSNER:</p> <p>6 Q. Was that another reason the DEA was 7 skeptical of manufacturer's quota requests?</p> <p>8 A. Yes.</p> <p>9 Q. Among the factors that the DEA would 10 look at in examining a mid-year quota change, 11 would they look at sales compared to inventory?</p> <p>12 A. Yes.</p> <p>13 Q. And so if a manufacturer was able to 14 show a lot of sales and no inventory, then that 15 might support an increase in their quota 16 authorization; is that right?</p> <p>17 MR. CHANDLER: Objection. Calls for 18 speculation. Incomplete hypothetical.</p> <p>19 MR. O'CONNOR: Objection.</p> <p>20 MS. McCLURE: Object to form. 21 Scope.</p> <p>22 MR. MASTERS: Objection to 23 highlighting part of the document rather than 24 the entire paragraph.</p> <p>25 MS. McCLURE: Objection as to the</p>	<p style="text-align: right;">Page 173</p> <p>1 And I am going to repeat the same 2 objection and object again to the fact that 3 this is a highly confidential document and as 4 counsel -- Mr. Chandler stated before, he 5 instructed his client not to answer and this is 6 outside the scope of the designations for which 7 the witness was designated to testify.</p> <p>8 BY MR. ELSNER:</p> <p>9 Q. I'm going to ask you to look at the 10 last page of the document here.</p> <p>11 The third to last paragraph just 12 under "total available," it reads: "Based on 13 the conversation with DEA recently, their 14 stated position is that Rhodes will not be 15 awarded additional quota allocation until we 16 generate sales and submit a new quota request. 17 My recommendation is to ship (sell) every 18 kilogram we can from Rhodes in April, hold back 19 only what we estimate R&D may want for 20 development purposes. Rhodes would then 21 prepare and submit a new quota request to DEA 22 on May 1st for 3,000-plus kilograms and a 50 23 percent inventory build allowance or a total of 24 4,500-plus kilograms."</p> <p>Did I read that correctly?</p>

<p style="text-align: right;">Page 174</p> <p>1 MS. NEWMARK: Objection.</p> <p>2 MR. O'CONNOR: Objection.</p> <p>3 MS. NEWMARK: Again to the use of</p> <p>4 this document.</p> <p>5 MR. ELSNER: Your objection is</p> <p>6 preserved. You don't need to give a speaking</p> <p>7 objection that lasts three minutes every time.</p> <p>8 MS. NEWMARK: I'm going to keep</p> <p>9 repeating my objection as long as you keep</p> <p>10 trying to violate the confidentiality order in</p> <p>11 this case and in the Kentucky case.</p> <p>12 MS. McCLURE: I will note for the</p> <p>13 record the inconsistent instruction from DEA</p> <p>14 counsel as to whether witnesses are or are not</p> <p>15 permitted to answer questions.</p> <p>16 MR. MASTERS: Objection.</p> <p>17 MR. CHANDLER: And I am going to</p> <p>18 object on scope grounds, and instruct the</p> <p>19 witness not to answer.</p> <p>20 Again, the witness is not designated</p> <p>21 to testify about individual determinations as</p> <p>22 to particular registrants, particular years,</p> <p>23 particular substances and I -- if you want to</p> <p>24 ask about a policy or a practice, that's fine,</p> <p>25 but I don't see any connection between this</p>	<p style="text-align: right;">Page 176</p> <p>1 MR. CHANDLER: You can answer</p> <p>2 without reference to the document.</p> <p>3 THE WITNESS: If a manufacturer came</p> <p>4 for a mid-year revision for a quota because it</p> <p>5 sold all that it had, DEA would consider that,</p> <p>6 but once again, with a skeptical eye and a look</p> <p>7 to third-party data to see that prescriptions</p> <p>8 were being filled.</p> <p>9 BY MR. ELSNER:</p> <p>10 Q. But it could potentially impact the</p> <p>11 quota authorization, correct?</p> <p>12 MS. McCLURE: Same objection.</p> <p>13 MR. CHANDLER: Same objection.</p> <p>14 MR. O'CONNOR: Objection.</p> <p>15 THE WITNESS: It could.</p> <p>16 MR. ELSNER: Why don't we take a</p> <p>17 quick break.</p> <p>18 THE VIDEOGRAPHER: We are going off</p> <p>19 the record. This is the end of Media Unit No.</p> <p>20 4. The time is 3:23.</p> <p>21 (A short recess was taken.)</p> <p>22 THE VIDEOGRAPHER: We are going back</p> <p>23 on the record. This is the start of Media Unit</p> <p>24 No. 5. The time is 3:44.</p> <p>25 You may proceed, Counsel.</p>
<p style="text-align: right;">Page 175</p> <p>1 document and the policy or practice.</p> <p>2 MR. ELSNER: I appreciate the</p> <p>3 objection. I just haven't asked the question</p> <p>4 yet.</p> <p>5 BY MR. ELSNER:</p> <p>6 Q. My question is, is that if a</p> <p>7 manufacturer was selling all the product that</p> <p>8 they have and then requesting a mid-year review</p> <p>9 saying that we sold all of our product and our</p> <p>10 inventory is down to nothing, would that</p> <p>11 potentially impact the DEA's decision to</p> <p>12 increase their quota?</p> <p>13 MR. CHANDLER: And --</p> <p>14 MR. O'CONNOR: Objection.</p> <p>15 MR. CHANDLER: -- I'm going to</p> <p>16 object on scope grounds, and if you are asking</p> <p>17 the question in the abstract separate from</p> <p>18 Exhibit 12, then I will allow the witness to</p> <p>19 answer.</p> <p>20 Subject to the further objection</p> <p>21 that it is vague, calls for speculation and</p> <p>22 it's an incomplete hypothetical.</p> <p>23 MS. McCLURE: Objection. Incomplete</p> <p>24 hypothetical. Objection to form, speculation</p> <p>25 and scope.</p>	<p style="text-align: right;">Page 177</p> <p>1 MR. ELSNER: Thank you.</p> <p>2 BY MR. ELSNER:</p> <p>3 Q. Ma'am, as you pointed out, the DEA</p> <p>4 didn't just rely on the manufacturer's</p> <p>5 information to set quota. The DEA also looked</p> <p>6 at prescription data; is that true?</p> <p>7 A. Correct.</p> <p>8 MR. O'CONNOR: Objection to form.</p> <p>9 BY MR. ELSNER:</p> <p>10 Q. And did that include data provided</p> <p>11 by IMS and later equivalence of that company?</p> <p>12 A. Yes.</p> <p>13 Q. And would you agree with me that if</p> <p>14 manufacturers and distributors of opioids had</p> <p>15 misled doctors and the public about the health</p> <p>16 benefits and the addictive nature of opioids</p> <p>17 they were manufacturing and distributing</p> <p>18 causing sales to rise, then the DEA's estimate</p> <p>19 of the medical need could be above the actual</p> <p>20 medical need in the United States?</p> <p>21 MR. CHANDLER: Objection.</p> <p>22 MS. McCLURE: Objection. Form.</p> <p>23 Speculation. Incomplete hypothetical. Vague.</p> <p>24 Compound. Foundation.</p> <p>25 THE WITNESS: Yes.</p>

<p style="text-align: right;">Page 178</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. And among the factors that could 3 impact quota and the medical need, if you turn 4 to -- back to Exhibit 10, which is a PowerPoint 5 and I will ask you to look at Page 28. This is 6 the DEA's PowerPoint again.</p> <p>7 And the heading on the top of the 8 PowerPoint says: "Factors hindering 9 determination of legitimate medical need."</p> <p>10 Did I read that correctly?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And one of those factors on 13 the bottom is an unusually aggressive, 14 innovative, persuasive marketing and promotion. 15 Would you agree that that would potentially 16 impact the determination of legitimate medical 17 need?</p> <p>18 MR. CHANDLER: Object to form.</p> <p>19 MR. O'CONNOR: Object to form.</p> <p>20 MS. McCLURE: Same objection. Speculation.</p> <p>22 THE WITNESS: It would definitely overestimate legitimate medical need.</p> <p>24 BY MR. ELSNER:</p> <p>25 Q. Okay. Now, the DEA doesn't have</p>	<p style="text-align: right;">Page 180</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. Okay. If you look at the notes at 3 the bottom of the slide under the heading: 4 "Unusually aggressive, innovative, persuasive 5 marketing promotion."</p> <p>6 Do you see where I am at?</p> <p>7 A. Yes.</p> <p>8 Q. The first bullet reads: "Much more 9 promotional money spent on OxyC than equivalent 10 products."</p> <p>11 Could that promotional money spent 12 on OxyContin impact the determination of 13 legitimate medical need of the DEA?</p> <p>14 MR. CHANDLER: Objection. Vague.</p> <p>15 MR. EPPICH: Objection. Foundation.</p> <p>16 Form. Outside the scope.</p> <p>17 MR. CHANDLER: Objection. Foundation. Form.</p> <p>19 THE WITNESS: Only if it impacted 20 physician's prescription writing.</p> <p>21 BY MR. ELSNER:</p> <p>22 Q. And there are a number of other 23 bullets here.</p> <p>24 The second one reads: "Scope of the 25 medical specialty groups promoted to the widest</p>
<p style="text-align: right;">Page 179</p> <p>1 control over the marketing and promotional 2 activities of manufacturers; is that correct?</p> <p>3 MR. O'CONNOR: Object to form.</p> <p>4 MR. CHANDLER: Objection. Scope.</p> <p>5 MS. McCLURE: Foundation.</p> <p>6 THE WITNESS: Correct.</p> <p>7 BY MR. ELSNER:</p> <p>8 Q. Now, this slide has some pictures in 9 it. It has a stuffed animal and it has a mug, 10 it reads: "The one to start with." And then 11 the other mug has "OxyContin" written on it.</p> <p>12 Do you see that?</p> <p>13 MR. EPPICH: Objection. Foundation.</p> <p>14 Speculation.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. ELSNER:</p> <p>17 Q. Are these some promotional items 18 that Purdue would send out?</p> <p>19 MS. McCLURE: Foundation.</p> <p>20 MS. NEWMARK: Objection. Foundation. Form.</p> <p>22 MR. EPPICH: Scope.</p> <p>23 MR. CHANDLER: Objection. Form.</p> <p>24 THE WITNESS: I'm unaware of the 25 promotional items that they sent out.</p>	<p style="text-align: right;">Page 181</p> <p>1 for OxyC."</p> <p>2 Next is: "IMS messaging site. Physicians heard use OxyC for moderate to severe pain, acute and chronic pain."</p> <p>5 Next one: "Effective pain relief, use it for everyone."</p> <p>7 Next one: "OxyC reports of diversion and abuse routinely downplayed."</p> <p>9 These are all items listed as factors that could hinder the determination of legitimate medical need in the DEA's presentation; is that true?</p> <p>13 MR. O'CONNOR: Objection. Form. Scope.</p> <p>15 MR. CHANDLER: Objection. Form.</p> <p>16 THE WITNESS: Correct.</p> <p>17 BY MR. ELSNER:</p> <p>18 Q. Do you agree with them?</p> <p>19 MR. CHANDLER: Objection. Scope. Form.</p> <p>21 THE WITNESS: If those statements 22 are true, they would impact estimations of 23 legitimate medical need.</p> <p>24 BY MR. ELSNER:</p> <p>25 Q. Okay. And if these extensive</p>

<p style="text-align: right;">Page 182</p> <p>1 marketing campaigns encouraged doctors to 2 prescribe and patients to seek opioids for the 3 treatment of ankle sprains and backaches and 4 all other types of nonchronic pain, and sales 5 increased dramatically, it would impact the 6 DEA's estimate of potential medical need 7 because it would impact the number of 8 prescription written, correct?</p> <p>9 MR. CHANDLER: Objection. Vague.</p> <p>10 Incomplete hypothetical. Form.</p> <p>11 MR. MASTERS: Form. Foundation.</p> <p>12 Speculation.</p> <p>13 MS. NEWMARK: Scope.</p> <p>14 MR. O'CONNOR: Objection. Form.</p> <p>15 THE WITNESS: DEA does not determine 16 which legitimate medical needs require 17 controlled substances and which ones do not. 18 That is up to the FDA and the physicians 19 themselves.</p> <p>20 BY MR. ELSNER:</p> <p>21 Q. If you turn to Page 29 in the 22 presentation.</p> <p>23 The top of the slide reads: "The 24 limitations of quotas."</p> <p>25 Did I read that right?</p>	<p style="text-align: right;">Page 184</p> <p>1 as factors that could limit -- under the 2 limitations of quotas, do you agree that 3 marketing these products to nontraditional pain 4 groups and spending massive promotional dollars 5 could impact the quota and the definition of 6 legitimate medical need?</p> <p>7 MR. O'CONNOR: Objection. Form.</p> <p>8 MR. CHANDLER: Objection. Form.</p> <p>9 Scope. Foundation. Form.</p> <p>10 THE WITNESS: They would limit 11 quota, yes.</p> <p>12 BY MR. ELSNER:</p> <p>13 Q. Okay. If -- you said, "they would 14 limit quota."</p> <p>15 Do you mean -- I just want to make 16 sure I understand. Are you saying that these 17 types of activities, they would limit the 18 ability to accurately determine quota; is that 19 what you mean?</p> <p>20 A. Correct.</p> <p>21 MR. CHANDLER: Objection. Scope.</p> <p>22 Foundation. Form.</p> <p>23 MR. O'CONNOR: Object to form.</p> <p>24 BY MR. ELSNER:</p> <p>25 Q. If you could turn to Page 11 of the</p>
<p style="text-align: right;">Page 183</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And it shows dollars in 3 thousands and it shows OxyContin reaching over 4 \$1.6 billion in total sales.</p> <p>5 Do you see that in the red bar?</p> <p>6 A. Yes.</p> <p>7 Q. And then on the bottom, there's some 8 notes from DEA and there is a heading that 9 says: "Drawbacks of quotas."</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. Then there is: "Marketing 13 promotional techniques," that's underlined.</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And it reads: "Massive promotional 17 dollars spent."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 Q. "Promoted to nontraditional pain 21 specialty groups implied and inferred OxyContin 22 messages to prescribers."</p> <p>23 Did I read that correctly?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. This presentation lists these</p>	<p style="text-align: right;">Page 185</p> <p>1 presentation.</p> <p>2 The title of this slide is:</p> <p>3 "Consumption of analgesics for the treatment of 4 moderate to severe pain."</p> <p>5 Is that what it says?</p> <p>6 A. Yes.</p> <p>7 Q. And it shows that the number of 8 prescriptions for the -- the number of 9 prescriptions for the treatment of moderate to 10 severe pain increased as a result of those 11 promotional activities from '98, '99 through 12 2002, correct?</p> <p>13 MR. CHANDLER: Objection. Scope.</p> <p>14 Foundation.</p> <p>15 MR. EPPICH: Objection. Foundation.</p> <p>16 Form.</p> <p>17 THE WITNESS: So it shows that 18 prescriptions increased.</p> <p>19 BY MR. ELSNER:</p> <p>20 Q. For the treatment of moderate to 21 severe pain, correct?</p> <p>22 A. Correct.</p> <p>23 Q. And consequently, the quota 24 authorization also increased, correct? In the red bars?</p>

<p style="text-align: right;">Page 186</p> <p>1 MR. CHANDLER: Objection. Form. 2 Foundation. 3 THE WITNESS: Yes. 4 BY MR. ELSNER: 5 Q. Okay. Now if the supply was limited 6 -- so I am done with the document now. 7 If the supply were limited, if you 8 decreased the quota, would that stop all 9 diversion? 10 MR. CHANDLER: Objection. Form. 11 THE WITNESS: No. 12 BY MR. ELSNER: 13 Q. It would simply mean that the gross 14 bulk amount of a particular gross drug type 15 would be less, right? 16 MR. CHANDLER: Objection. Form. 17 THE WITNESS: Can you repeat the 18 question. 19 BY MR. ELSNER: 20 Q. It would simply mean that gross bulk 21 amount of a particular gross drug type would be 22 less, correct? 23 MR. CHANDLER: Same objection. 24 MR. O'CONNOR: Object to form. 25 THE WITNESS: Correct.</p>	<p style="text-align: right;">Page 188</p> <p>1 MR. CHANDLER: Object to form. 2 MR. O'CONNOR: Object to form. 3 THE WITNESS: It reduces the amount 4 of material available, period. 5 BY MR. ELSNER: 6 Q. Across the board? 7 A. Across the board. 8 MR. EPPICH: Object to form. 9 MS. McCLURE: All the same 10 objections. 11 BY MR. ELSNER: 12 Q. In 2001, the DEA administrator Donny 13 Marshall testified before Congress. 14 Are you familiar with that 15 testimony? 16 A. I am. 17 Q. Okay. 18 MR. ELSNER: I'm going to mark it as 19 the next exhibit. 20 (Deposition Exhibit 13 was marked 21 for identification.) 22 BY MR. ELSNER: 23 Q. I'm going to ask you to turn to Page 24 115 of 228. 25 MS. McCLURE: Can you read the Bates</p>
<p style="text-align: right;">Page 187</p> <p>1 BY MR. ELSNER: 2 Q. Okay. And when it was reduced, it 3 would be reduced both for the illicit market 4 and the licit market, correct? 5 MR. MASTERS: Objection. Scope. 6 MS. McCLURE: Objection. Form. 7 Speculation. Foundation. 8 MR. CHANDLER: Objection. Form. 9 THE WITNESS: The quota is only for 10 the legitimate medical needs and so it's only 11 for the legitimate market. 12 BY MR. ELSNER: 13 Q. But we recognize that pills are 14 diverted, correct? 15 MR. O'CONNOR: Objection. Form. 16 MS. McCLURE: Foundation. 17 MR. CHANDLER: Objection. 18 THE WITNESS: Yes. 19 BY MR. ELSNER: 20 Q. And so if we reduce the size of the 21 quota simply reduces the pool of available 22 drugs, both to the licit and illicit users of 23 that drug, correct? 24 MS. McCLURE: Form. Foundation. 25 Speculation. Scope.</p>	<p style="text-align: right;">Page 189</p> <p>1 number into the record. 2 MR. ELSNER: There is not a Bates 3 number but this is the -- it's testimony of 4 Donny Marshall before a subcommittee of the 5 committee of appropriations in the House of 6 Representatives in 2001. 7 BY MR. ELSNER: 8 Q. And about in the middle of the page, 9 there is a paragraph that -- it begins with: 10 "We begin to see this problem." 11 Do you see where I am at? 12 A. Yes. 13 Q. Okay. And he is asked about 14 oxycodone and he says: "We begin to see this 15 problem as a result of some developments that 16 began four or five years ago. What we saw 17 about four or five years in 1996 or 18 thereabouts, was that the AMA and a number of 19 pain management groups that made the case and 20 contended that we are under-treating pain in 21 this country or that we are not effectively 22 treating pain in this country." 23 Did I read that correctly? 24 A. Yes. 25 Q. And if you go to the next page, in</p>

<p style="text-align: right;">Page 190</p> <p>1 the middle of the paragraph, it starts at the 2 third full paragraph: "We are asking the 3 industry to do several things." 4 Do you see where I am at? 5 A. Yes. 6 Q. It says: "No. 1, we are asking that 7 the company do a more balanced approach in 8 their marketing of this drug. We are asking 9 them to educate doctors and patients about the 10 dangers of the drug. We are asking them not to 11 advertise in such a way that gives a physician, 12 for instance, who is not well-trained in pain 13 management, it gives that physician the 14 impression that this might be the painkiller of 15 first resort rather than the painkiller of last 16 resort. We are asking them and others perhaps 17 to come up with what we refer to as a 18 restricted distribution, in other words, 19 recommend that doctors only prescribe and 20 pharmacists only distribute this for certain 21 types of pain, so that the kidney stone patient 22 may get a different version of it, but the 23 terminal cancer patient may well get the 160 24 milligram oxycodone." 25 Do you see that?</p>	<p style="text-align: right;">Page 192</p> <p>1 MR. ELSNER: Mark this next document 2 as the next exhibit. 3 (Deposition Exhibit 14 was marked 4 for identification.) 5 MR. ELSNER: It bears the Bates 6 range PPLPC045 and then a bunch of zeros, 5405 7 through 5425. 8 BY MR. ELSNER: 9 Q. Was the DEA aware -- 10 MS. NEWMARK: I will object to the 11 use of this document. I have not gotten a 12 chance to look through it but it appears to be 13 a Purdue produced e-mail and you are showing it 14 to the witness in violation of the protective 15 order as it's marked confidential, and you did 16 not seek permission from Purdue to show this to 17 the witness. 18 MR. ELSNER: First, your 19 understanding of the protective order is wrong. 20 Section 33M states that there is only a 21 restriction in sharing it with another -- an 22 employee of another party. This is not another 23 party in the litigation. So your objection is 24 completely wrong. 25 Furthermore, the Government has</p>
<p style="text-align: right;">Page 191</p> <p>1 A. Yes. 2 Q. Did I read it correctly? 3 A. Yes. 4 Q. Okay. And then in the second to 5 last paragraph, he states: "Frankly, the 6 manufacturer of this, they have met us on some 7 of these issues, on others, they have not met 8 us." 9 And then he says: "And I have to 10 tell you, sir, that we need more cooperation 11 from that company, and if we cannot find some 12 more middle ground in this area, I am seriously 13 considering rolling back the corners of the 14 quotas that the DEA set, rolling back those 15 quotas to 1996 levels until we find ways to 16 control this." 17 Did I read this correctly? 18 A. Yes. 19 Q. Were you aware that the DEA was 20 considering rolling back quotas to 1996 levels 21 for oxycodone? 22 MR. CHANDLER: Objection. Scope. 23 MR. O'CONNOR: Objection. 24 THE WITNESS: I am aware that it had 25 been considered.</p>	<p style="text-align: right;">Page 193</p> <p>1 signed the confidentiality order and they're -- 2 and I am entitled to use it in this deposition 3 and I don't need to ask for permission. 4 Secondly, the repeated extensive 5 objections are interfering with the flow of the 6 deposition unnecessarily, and I think 7 intentionally, and I ask you simply to say 8 objection. Your objections are always 9 preserved and you can raise them at a later 10 time. 11 MS. NEWMARK: Counsel, I am entitled 12 to object to whenever you ask a question that 13 is objectionable. Furthermore, under Section 14 33H of the confidentiality order, if a designee 15 -- you're required to give the designee party 16 notice of your intent to disclose a document to 17 state or federal law enforcement agencies, even 18 if they have completed the certification in 19 Exhibit A and the acknowledgement to be bound, 20 and if the designating party, which here is 21 Purdue, objects to the disclosure, then the 22 designating party may request a meet and confer 23 and resolve the protective order from the 24 Court. 25 MR. ELSNER: This is not that</p>

<p style="text-align: right;">Page 194</p> <p>1 situation. I'm not disclosing it for that 2 situation.</p> <p>3 MS. NEWMARK: This is that 4 situation, and we can call Colin right now if 5 you want to have a dispute about this.</p> <p>6 MR. ELSNER: Well, we have a dispute 7 about it, but we are not going to waste any 8 more time. Your objection is preserved.</p> <p>9 MS. NEWMARK: I'm going to continue 10 to object to your use of this document and 11 furthermore, it is outside the scope of what 12 this witness is permitted to testify about 13 today.</p> <p>14 BY MR. ELSNER:</p> <p>15 Q. Ma'am, were you aware that Purdue, 16 in response to Mr. Marshall's testimony, began 17 writing letters to its customers, to pain 18 management groups and to members of Congress?</p> <p>19 MR. O'CONNOR: Objection. Form. 20 Scope.</p> <p>21 MR. CHANDLER: Objection. Scope.</p> <p>22 MS. NEWMARK: Objection. 23 Foundation.</p> <p>24 THE WITNESS: The DEA is aware of 25 that.</p>	<p style="text-align: right;">Page 196</p> <p>1 Did I read that correctly? 2 A. Yes. 3 Q. Okay. It reads that -- under that: 4 "In human terms, such a rollback would mean, 5 No. 1, in 1996, the amount of oxycodone 6 allocated to Purdue allowed us to supply enough 7 OxyContin to fill approximately 29,000 8 prescriptions per year. In 2000, the amount of 9 oxycodone allocated to Purdue allowed us to 10 supply enough OxyContin to fill approximately 11 5.4 million prescriptions a year." 12 It then says, under Item 3: "If the 13 quota were reduced as suggested by Mr. 14 Marshall, we would not be able to supply 95 15 percent of the demand for OxyContin. 19 out of 16 every 20 patients would be unable to fill their 17 doctor's prescriptions."</p> <p>18 Did I read that correctly? 19 A. Yes. 20 Q. On the next page, the second 21 paragraph, the first line reads: "If the DEA 22 were to impose even a small restriction on 23 Purdue's quota for oxycodone, the war on drugs 24 would turn into a war on people in pain." 25 Did I read that correctly?</p>
<p style="text-align: right;">Page 195</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. Okay. I'm going to ask you to look 3 at the second page of the document. This is 4 one of the drafts.</p> <p>5 MS. NEWMARK: So again, I'm going to 6 object to the use of this document.</p> <p>7 MR. ELSNER: Your objection is 8 preserved.</p> <p>9 MS. NEWMARK: That it's violating 10 the protective order in this case, and I'm 11 going to keep objecting as long as you keep 12 violating the protective order.</p> <p>13 MR. ELSNER: I'm going to ask 14 questions on this document. Your objection is 15 preserved. You don't need to raise it every 16 single question that I ask. It's preserved. 17 You can simply say objection.</p> <p>18 BY MR. ELSNER:</p> <p>19 Q. I'm going to ask you to look at the 20 middle of this document, at the end of the 21 second full paragraph.</p> <p>22 It reads: "The 1996 level would 23 represent a 95 percent reduction in raw 24 material allowing only one prescription of 20 25 to be filled."</p>	<p style="text-align: right;">Page 197</p> <p>1 A. Yes. 2 Q. Was the DEA aware that Purdue was 3 sending letters out to its customers telling 4 them that the DEA was engaged in a war on 5 people in pain?</p> <p>6 MR. O'CONNOR: Objection. Form. 7 Scope.</p> <p>8 MR. CHANDLER: Objection.</p> <p>9 MS. NEWMARK: Objection. 10 Foundation.</p> <p>11 MR. O'CONNOR: Can the DOJ instruct 12 the witness not to answer on the basis of 13 scope.</p> <p>14 MR. CHANDLER: No. The witness can 15 answer.</p> <p>16 THE WITNESS: I'm not sure we -- DEA 17 was aware of it going to actual patients. We 18 knew it went to Congress.</p> <p>19 BY MR. ELSNER:</p> <p>20 Q. And the DEA wasn't engaged in a war 21 on people in pain, was it?</p> <p>22 MR. O'CONNOR: Objection. Scope. 23 MR. CHANDLER: Objection. 24 Foundation.</p> <p>25 THE WITNESS: No.</p>

<p style="text-align: right;">Page 198</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. You were trying to set the 3 legitimate medical need for the country, 4 correct?</p> <p>5 A. Correct.</p> <p>6 MR. EPPICH: Objection. Vague.</p> <p>7 BY MR. ELSNER:</p> <p>8 Q. Among the items that the DEA was 9 attempting to work with manufacturers on, which 10 included a more balanced approach to marketing, 11 better education, better -- less advertising, 12 those items including the addictive nature of 13 the drug are not revealed in this letter, are 14 they?</p> <p>15 MR. O'CONNOR: Objection. Form. 16 Scope.</p> <p>17 MR. CHANDLER: Objection. Form.</p> <p>18 THE WITNESS: No, it does not look 19 like it.</p> <p>20 BY MR. ELSNER:</p> <p>21 Q. If you turn to the next letter, the 22 next draft letter, you mentioned that you were 23 aware that letters had been sent from Purdue to 24 members of Congress.</p> <p>25 This is a draft letter to be sent to</p>	<p style="text-align: right;">Page 200</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. If you look at the bottom of the 3 first page of this exhibit, there is a dash 8 4 there.</p> <p>5 And it reads: "A version of this 6 letter should go to pain physicians as well. 7 This is a clear attack on the pain movement. 8 There can be no other interpretation."</p> <p>9 Did I read that correctly?</p> <p>10 A. Yes.</p> <p>11 Q. And was the DEA trying to attack the 12 pain movement by trying to set the appropriate 13 quota authorization for oxycodone?</p> <p>14 MR. O'CONNOR: Objection.</p> <p>15 MR. EPPICH: Objection. Scope.</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. ELSNER:</p> <p>18 Q. The DEA was just simply trying to 19 correctly determine the legitimate medical need 20 for oxycodone; is that right?</p> <p>21 MR. O'CONNOR: Objection.</p> <p>22 MR. EPPICH: Objection. Calls for 23 speculation.</p> <p>24 MR. CHANDLER: Objection. Form.</p> <p>25 THE WITNESS: So the DEA was hoping</p>
<p style="text-align: right;">Page 199</p> <p>1 Congressional members in North Carolina, and in 2 this letter, Purdue is threatening that they 3 are going to close their plant in Wilson, North 4 Carolina, if the 1996 rollback occurs.</p> <p>5 Was the DEA aware of that?</p> <p>6 MR. O'CONNOR: Objection. Form. 7 Scope. Mischaracterizes prior testimony.</p> <p>8 THE WITNESS: DEA knew that 9 manufacturers tended to threaten Congress with 10 closing their facilities.</p> <p>11 BY MR. ELSNER:</p> <p>12 Q. Okay. If we turn to --</p> <p>13 MR. ELSNER: Mark this as the next 14 exhibit.</p> <p>15 (Deposition Exhibit 15 was marked 16 for identification.)</p> <p>17 MR. ELSNER: This is another Purdue 18 document. Your objections are preserved.</p> <p>19 MS. NEWMARK: I'm going to repeat my 20 objection. Obviously an objection to the use 21 of the prior document, the document is under 22 the protective order in this case and counsel's 23 violating Section 33H of the protective order 24 by continuing to use all of these Purdue 25 documents that are clearly marked confidential.</p>	<p style="text-align: right;">Page 201</p> <p>1 to find that the FDA would provide better data 2 for legitimate medical need, yes, as they are 3 the agency required to do so.</p> <p>4 BY MR. ELSNER:</p> <p>5 Q. But the DEA was not trying to attack 6 the pain movement in trying to set the right 7 quota, correct?</p> <p>8 MR. O'CONNOR: Objection. Form. 9 THE WITNESS: Correct.</p> <p>10 BY MR. ELSNER:</p> <p>11 Q. Now, under No. 10, it says: "The 12 AAFP," this is the American Association of 13 Family Practitioners, "would be very interested 14 in this testimony. Want me to call Henely or 15 to send him an e-mail this weekend with the 16 testimony? He will be incensed at the 17 suggestion that prescribing will be limited."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 Q. Now one of the things that the DEA 21 was hoping to work cooperatively with the 22 industry with, was to restrict the number of 23 doctors who could prescribe this medication to 24 those who specialized in pain management, 25 correct?</p>

<p style="text-align: right;">Page 202</p> <p>1 MR. O'CONNOR: Object to form. 2 Scope. 3 MR. CHANDLER: Objection to scope. 4 I will instruct the witness not to answer that 5 one. 6 BY MR. ELSNER: 7 Q. Was the DEA aware that Purdue was 8 sending letters to pain physicians and to pain 9 -- patient advocacy groups to oppose Mr. 10 Marshall's testimony in the quota 11 authorization? 12 MR. O'CONNOR: Objection. Form. 13 Scope. 14 THE WITNESS: I'm unaware that the 15 DEA knew about that. 16 BY MR. ELSNER: 17 Q. Okay. If you turn to the second to 18 the last page of the document, the document 19 bearing the Bates number -- the last numbers 20 being 5403. 21 There is a comment there on the 22 right-hand side and it reads: "Again, if this 23 becomes public, do we think that our employees 24 will understand that we don't expect the 25 reduction in quota to happen, wouldn't it be</p>	<p style="text-align: right;">Page 204</p> <p>1 THE VIDEOGRAPHER: We are back on 2 the record. The time is 4:34. 3 You may proceed, Counsel. 4 (Deposition Exhibit 16 was marked 5 for identification.) 6 BY MR. ELSNER: 7 Q. I placed before you Exhibit 16 which 8 is the letter that was written by the American 9 Academy of Pain Management to the DEA, Donnie 10 Marshall, on June 8, 2001. 11 Do you see that? 12 A. Yes. 13 Q. And this is in response to Mr. 14 Marshall's testimony, and if you go to the 15 middle of the second paragraph, it begins: 16 "CSA requirement." 17 Do you see where I am at? "For 18 determination of legitimate medical need." 19 You can see it on the screen 20 perhaps? 21 A. Yes. 22 Q. Okay. It reads: "CSA requirement 23 for determination of legitimate medical need is 24 based on the undisputed position that patients 25 and pharmacies should be able to obtain</p>
<p style="text-align: right;">Page 203</p> <p>1 better to make this point verbally over the 2 telephone rather than in a letter, which may be 3 leaked intentionally or unintentionally. I'm 4 sure that between us three, we can get 5 eventually every Senator and Congressman we 6 want to talk to us on the phone in the next 72 7 hours."</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes.</p> <p>10 Q. Was the DEA aware that Purdue had 11 done an outreach by phone to members of 12 Congress?</p> <p>13 MR. O'CONNOR: Object to form.</p> <p>14 MR. CHANDLER: Objection to form.</p> <p>15 Foundation.</p> <p>16 THE WITNESS: DEA was aware that 17 there was an outreach to Congress, not the form 18 that it took.</p> <p>19 BY MR. ELSNER:</p> <p>20 Q. If you turn to --</p> <p>21 MR. ELSNER: Actually, can we go off 22 the record real quick.</p> <p>23 THE VIDEOGRAPHER: We are going off 24 the record. The time is 4:15.</p> <p>25 (A short recess was taken.)</p>	<p style="text-align: right;">Page 205</p> <p>1 sufficient quantities of any Schedule II drug 2 to fill prescriptions. A therapeutic drug 3 should be available to patients when they need 4 it."</p> <p>5 Did I read that correctly?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And then on the next page in 8 the second full paragraph, second sentence, it 9 states -- in the second sentence: "For 30 10 years, the U.S. Government has waged a war 11 against this epidemic problem with limited 12 success, choking off the supply of one opioid 13 analgesic oxycodone does not solve the 14 underlying problem of consumer demand. In 15 fact, declaring oxycodone highly dangerous only 16 adds to its mystique and desirability by drug 17 abusers and addicts."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 Q. In the next paragraph, it says that: 21 "The manufacturer of the most highly sought 22 after form of oxycodone, Purdue Pharma L.P., is 23 one of the most ethical pharmaceutical 24 companies in the United States."</p> <p>25 Did I read that correctly?</p>

<p style="text-align: right;">Page 206</p> <p>1 A. Yes.</p> <p>2 Q. When the DEA received this letter,</p> <p>3 did it know that Purdue Pharma had provided</p> <p>4 financial support for this organization?</p> <p>5 MS. MCCLURE: Objection.</p> <p>6 Foundation. Form.</p> <p>7 MR. O'CONNOR: Objection.</p> <p>8 THE WITNESS: I do not think DEA was</p> <p>9 aware of that.</p> <p>10 BY MR. ELSNER:</p> <p>11 Q. The next sentence in that paragraph,</p> <p>12 it says: "Unlike many other pharmaceutical</p> <p>13 companies, Purdue Pharma consistently offers</p> <p>14 the best continuing medical education</p> <p>15 conferences, does not engage in covert bribery</p> <p>16 and even discourages its representatives from</p> <p>17 providing alcohol."</p> <p>18 This was at least five years before</p> <p>19 Purdue pled guilty in federal court; is that</p> <p>20 correct?</p> <p>21 MR. O'CONNOR: Objection.</p> <p>22 MR. CHANDLER: Objection. Scope.</p> <p>23 MS. MCCLURE: Objection. Form.</p> <p>24 MS. NEWMARK: Objection. Form.</p> <p>25 MR. EPPICH: Foundation.</p>	<p style="text-align: right;">Page 208</p> <p>1 Foundation. Scope.</p> <p>2 MR. CHANDLER: Objection. Form.</p> <p>3 Unless you want the witness to spend</p> <p>4 the next few minutes reading through the entire</p> <p>5 letter.</p> <p>6 You can answer.</p> <p>7 THE WITNESS: I haven't read the</p> <p>8 full letter but -- so I don't know.</p> <p>9 BY MR. ELSNER:</p> <p>10 Q. I will represent to you that it</p> <p>11 doesn't, but in April of 2018 --</p> <p>12 MR. ELSNER: Can I see -- we will</p> <p>13 mark this as the next exhibit.</p> <p>14 (Deposition Exhibit 17 was marked</p> <p>15 for identification.)</p> <p>16 BY MR. ELSNER:</p> <p>17 Q. In April of 2018, the DEA published</p> <p>18 a notice of proposed rulemaking related to</p> <p>19 quotas, and if you look on the summary, it</p> <p>20 reads: "The Drug Enforcement Administration is</p> <p>21 publishing this proposed rule to strengthen</p> <p>22 controls over diversion of controlled</p> <p>23 substances and make other improvements to the</p> <p>24 quota management regulatory system for their</p> <p>25 production, manufacturing and procurement of</p>
<p style="text-align: right;">Page 207</p> <p>1 THE WITNESS: I don't remember the</p> <p>2 exact year that they were in court.</p> <p>3 BY MR. ELSNER:</p> <p>4 Q. You do remember that Purdue has pled</p> <p>5 guilty to a felony of misbranding their drug</p> <p>6 with an intent to defraud and mislead?</p> <p>7 MR. CHANDLER: Objection. Scope.</p> <p>8 MS. NEWMARK: Objection.</p> <p>9 MR. O'CONNOR: Objection.</p> <p>10 BY MR. ELSNER:</p> <p>11 Q. Are you aware of that?</p> <p>12 A. Yes.</p> <p>13 Q. This wasn't the only letter that DEA</p> <p>14 received in response to Mr. Marshall's</p> <p>15 testimony, was it?</p> <p>16 MR. O'CONNOR: Objection. Form.</p> <p>17 MR. CHANDLER: Objection.</p> <p>18 Foundation. Form.</p> <p>19 THE WITNESS: Not that I'm aware of.</p> <p>20 BY MR. ELSNER:</p> <p>21 Q. And the letter doesn't indicate,</p> <p>22 does it, that Purdue had given financial</p> <p>23 support to this organization, the American</p> <p>24 Academy of Pain Management, does it?</p> <p>25 MR. O'CONNOR: Objection. Form.</p>	<p style="text-align: right;">Page 209</p> <p>1 controlled substances."</p> <p>2 Did I read that correctly?</p> <p>3 A. Yes.</p> <p>4 Q. And the purpose in the third column</p> <p>5 on the first page in the second full paragraph,</p> <p>6 where it starts: "The current regulations."</p> <p>7 Do you see where I am at?</p> <p>8 A. Yes.</p> <p>9 Q. "The current regulations issued</p> <p>10 initially in 1971 need to be updated to reflect</p> <p>11 changes in the manufacture of controlled</p> <p>12 substances, changing patterns of substance</p> <p>13 abuse and markets in illicit drugs, and the</p> <p>14 challenges presented by the current national</p> <p>15 crisis of controlled substance abuse. This</p> <p>16 proposed rule modifies the regulations to</p> <p>17 strengthening controls over diversion."</p> <p>18 Was that the intent?</p> <p>19 MR. O'CONNOR: Objection.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. ELSNER:</p> <p>22 Q. And if you go to the next page in</p> <p>23 the regulations, in the second full paragraph</p> <p>24 beginning with "first."</p> <p>25 Do you see where I am at?</p>

<p style="text-align: right;">Page 210</p> <p>1 A. Yes.</p> <p>2 Q. It reads: "First, it would" --</p> <p>3 MR. CHANDLER: I'm going to object</p> <p>4 to the characterization of this document as the</p> <p>5 regulations.</p> <p>6 MR. ELSNER: I didn't mean to</p> <p>7 suggest. I meant the proposed regulation.</p> <p>8 MR. CHANDLER: I just wanted to be</p> <p>9 clear.</p> <p>10 MR. ELSNER: No problem.</p> <p>11 BY MR ELSNER:</p> <p>12 Q. The proposed regulation as expressed</p> <p>13 here in that paragraph reads: "First, it would</p> <p>14 add to the list the extent of any diversion of</p> <p>15 the controlled substance in the class."</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Is this the first time that</p> <p>19 diversion is expressly mentioned in the statute</p> <p>20 or in the regulatory scheme related to quotas?</p> <p>21 MR. EPPICH: Objection to form.</p> <p>22 Foundation. Vague.</p> <p>23 THE WITNESS: Yes.</p> <p>24 BY MR. ELSNER:</p> <p>25 Q. Okay. And so prior to this, there</p>	<p style="text-align: right;">Page 212</p> <p>1 customer identities and the amounts of</p> <p>2 controlled substances sold to each customer."</p> <p>3 Did I read that correctly?</p> <p>4 A. Yes.</p> <p>5 Q. Is this the first time where the DEA</p> <p>6 has -- where there is a proposed rule for the</p> <p>7 DEA to expressly consider customer information</p> <p>8 from manufacturers?</p> <p>9 MR. O'CONNOR: Objection.</p> <p>10 Foundation.</p> <p>11 MR. EPPICH: Objection. Foundation.</p> <p>12 Scope.</p> <p>13 THE WITNESS: I don't understand the</p> <p>14 question.</p> <p>15 BY MR. ELSNER:</p> <p>16 Q. Okay. The proposed rule provides</p> <p>17 that manufacturers could -- clarifies that the</p> <p>18 manufacturers may be required to provide</p> <p>19 information about their customers; is that</p> <p>20 right?</p> <p>21 A. Correct.</p> <p>22 Q. Why was that important?</p> <p>23 MR. CHANDLER: Objection to form.</p> <p>24 MR. O'CONNOR: Objection.</p> <p>25 MR. CHANDLER: Scope.</p>
<p style="text-align: right;">Page 211</p> <p>1 was no expressed list or item in any of the</p> <p>2 regulations related to quota that mentioned</p> <p>3 diversion; is that right?</p> <p>4 MR. O'CONNOR: Objection.</p> <p>5 THE WITNESS: Correct.</p> <p>6 BY MR. ELSNER:</p> <p>7 Q. Okay. In the end of the -- say, the</p> <p>8 -- the proposed regulation also expressly</p> <p>9 permits the DEA to consider state's relevant</p> <p>10 data from its prescription monitoring program;</p> <p>11 is that true?</p> <p>12 MR. CHANDLER: Objection. Vague.</p> <p>13 THE WITNESS: To allow DEA to</p> <p>14 consider data from the states, yes.</p> <p>15 BY MR. ELSNER:</p> <p>16 Q. And the other thing that it</p> <p>17 expressly clarified at the bottom of the second</p> <p>18 column on this page, the last full paragraph.</p> <p>19 Do you see where I'm at?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. It reads: "The proposed rule</p> <p>22 would amend Section 1303.12(b) to clarify that</p> <p>23 the administrator may require additional</p> <p>24 comparable information from applicants that may</p> <p>25 help to detect or prevent diversion including</p>	<p style="text-align: right;">Page 213</p> <p>1 THE WITNESS: One factor that arose</p> <p>2 with this proposed rule was to remind</p> <p>3 manufacturers of their requirements to know</p> <p>4 their customers.</p> <p>5 BY MR. ELSNER:</p> <p>6 Q. And why were you reminding</p> <p>7 manufacturers of that responsibility?</p> <p>8 MR. O'CONNOR: Objection. Form.</p> <p>9 Scope.</p> <p>10 THE WITNESS: So that the</p> <p>11 manufacturers would not be surprised when we</p> <p>12 said -- we suggested that they did not know</p> <p>13 their customers.</p> <p>14 BY MR. ELSNER:</p> <p>15 Q. Sorry. Go ahead.</p> <p>16 A. No.</p> <p>17 Q. Okay. And that's one of the</p> <p>18 requirements under the Controlled Substances</p> <p>19 Act, right? In any event, for manufacturers to</p> <p>20 know their customers?</p> <p>21 MR. O'CONNOR: Objection. Form.</p> <p>22 Scope.</p> <p>23 MR. CHANDLER: Objection. Scope.</p> <p>24 THE WITNESS: It is part of the</p> <p>25 regulatory framework.</p>

<p style="text-align: right;">Page 214</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. In response to this proposed 3 rulemaking, the DEA also received comments.</p> <p>4 MR. ELSNER: I will mark this as an 5 exhibit.</p> <p>6 (Deposition Exhibit 18 was marked 7 for identification.)</p> <p>8 BY MR. ELSNER:</p> <p>9 Q. One of the comments was from the 10 PHRMA which is on the third page.</p> <p>11 Do you see that?</p> <p>12 MS. NEWMARK: I will object to the 13 use of this document as violating the 14 protective order in this case and I repeat all 15 my prior objections.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. ELSNER:</p> <p>18 Q. And on the second page of that 19 letter, it reads "under diversion and 20 legitimate medical need."</p> <p>21 "We're concerned that the DEA seems 22 to conflate legitimate need for opioid 23 treatment with legitimate use of opioids."</p> <p>24 Do you see that?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 216</p> <p>1 THE WITNESS: So that piece suggests 2 that those are two separate factors that should 3 be considered.</p> <p>4 BY MR. ELSNER:</p> <p>5 Q. And so even in 2018, there were 6 still objections being raised by pain 7 management groups and others to the reminders 8 from the DEA to manufacturers to know their 9 customers and provide that data to the DEA, 10 correct?</p> <p>11 MR. O'CONNOR: Objection. Form. Scope.</p> <p>13 MR. CHANDLER: Objection. Form. Scope.</p> <p>15 THE WITNESS: I don't understand the question.</p> <p>17 BY MR. ELSNER:</p> <p>18 Q. Even in 2018, as late as that, there 19 were still objections by pain management groups 20 and others to the DEA's proposed rulemaking 21 adding diversion as one of the criteria to 22 consider, correct?</p> <p>23 MR. CHANDLER: I'm going to renew my objection.</p> <p>25 MR. O'CONNOR: Objection.</p>
<p style="text-align: right;">Page 215</p> <p>1 Q. And then further down, it reads -- 2 the sentence beginning: "However, illegitimate 3 use of diverted controlled substances."</p> <p>4 Do you see that?</p> <p>5 A. No. Hold on a sec.</p> <p>6 Q. Take your time.</p> <p>7 A. Yes.</p> <p>8 Q. It says: "However, illegitimate use 9 of diverted controlled substances does not 10 extinguish legitimate need for a drug. For 11 example, if someone steals a pain patient's 12 legally prescribed opioid, the pain patient 13 still has a legitimate need for opioid, even 14 though some of the opioids were diverted for 15 illegitimate uses."</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. And so what is being argued here is 19 that -- that diversion does not affect need; is 20 that a fair summary?</p> <p>21 MR. O'CONNOR: Object to form.</p> <p>22 MR. CHANDLER: Objection.</p> <p>23 MS. McCLURE: Object to form.</p> <p>24 MR. EPPICH: Object to form.</p> <p>25 Mischaracterization of the document.</p>	<p style="text-align: right;">Page 217</p> <p>1 THE WITNESS: They submitted 2 comments objecting, yes.</p> <p>3 BY MR. ELSNER:</p> <p>4 Q. And were you aware -- this document 5 was produced to us by Purdue and if you look at 6 the very first page, you can see there is an 7 e-mail from Purdue attaching the letter to the 8 DEA.</p> <p>9 Was the DEA aware that Purdue was 10 encouraging letters like this to be written to 11 the DEA?</p> <p>12 MR. CHANDLER: Objection. Form. Foundation. Characterization of the document.</p> <p>14 MR. O'CONNOR: Objection. Form.</p> <p>15 MR. CHANDLER: Scope.</p> <p>16 MR. O'CONNOR: Scope and foundation.</p> <p>17 THE WITNESS: DEA was not aware.</p> <p>18 MR. ELSNER: Go off the record for a 19 minute.</p> <p>20 THE VIDEOGRAPHER: We are going off 21 the record. The time is 4:51. (A short recess was taken.)</p> <p>23 THE VIDEOGRAPHER: We are back on 24 the record. The time is 4:55.</p> <p>25 You may proceed, Counsel.</p>

<p style="text-align: right;">Page 218</p> <p>1 BY MR. ELSNER:</p> <p>2 Q. Earlier in the deposition, you were 3 asked a question that -- during the years that 4 you approved the quota numbers, did you feel 5 that they reflected the medical need of the 6 United States?</p> <p>7 Do you remember that line of 8 questioning?</p> <p>9 A. Yes.</p> <p>10 MR. CHANDLER: Objection.</p> <p>11 Mischaracterizes the prior question.</p> <p>12 MR. O'CONNOR: Objection.</p> <p>13 BY MR. ELSNER:</p> <p>14 Q. And you answered that you believed 15 that when you were approving quota allocations, 16 they were based on legitimate medical need.</p> <p>17 Do you remember that testimony?</p> <p>18 MR. CHANDLER: Objection.</p> <p>19 Mischaracterizes prior testimony.</p> <p>20 MR. O'CONNOR: Objection.</p> <p>21 THE WITNESS: So when I approved 22 quota, it was for a legitimate medical need or 23 scientific or research purposes or export or 24 inventory.</p> <p>25 BY MR. ELSNER:</p>	<p style="text-align: right;">Page 220</p> <p>1 A. Hello.</p> <p>2 Q. I will try to be quick. 3 Could you turn to Exhibit No. 10, 4 please.</p> <p>5 When counsel for plaintiffs asked 6 you some questions about this document, he 7 represented that it was delivered in 2003.</p> <p>8 Do you recall that?</p> <p>9 A. Yes, that's what he stated.</p> <p>10 Q. Where were you in 2003?</p> <p>11 A. I was not at DEA.</p> <p>12 Q. Did you have any involvement in 13 preparing this presentation?</p> <p>14 A. No, I did not.</p> <p>15 Q. Do you know who prepared the 16 presentation?</p> <p>17 A. No, I do not.</p> <p>18 Q. Had you ever seen this presentation 19 before today?</p> <p>20 A. Not this one, no.</p> <p>21 Q. And can you personally vouch for any 22 of the information contained in this 23 presentation?</p> <p>24 MR. ELSNER: Objection.</p> <p>25 THE WITNESS: I have not reviewed</p>
<p style="text-align: right;">Page 219</p> <p>1 Q. When you approved those quota 2 allocation, you were doing that based on the 3 information that you had available to you and 4 to the office of the DEA, correct?</p> <p>5 MR. O'CONNOR: Objection Form</p> <p>6 THE WITNESS: Yes</p> <p>7 BY MR. ELSNER:</p> <p>8 Q. And you did your very best with the 9 information that you had to make that 10 determination; is that true?</p> <p>11 MR. O'CONNOR: Objection</p> <p>12 THE WITNESS: Yes</p> <p>13 MR. ELSNER: I will pass the witness 14 at this time Go off the record</p> <p>15 THE VIDEOGRAPHER: We are going off 16 the record This is the end of Media Unit No 17 5 The time is 4:56 18 (A short recess was taken)</p> <p>19 THE VIDEOGRAPHER: We are going back 20 on the record This is the beginning of Media 21 Unit No 6 The time is 5:23 22 You may proceed, Counsel</p> <p>23 FURTHER EXAMINATION BY COUNSEL FOR DEFENDANTS</p> <p>24 BY MR. O'CONNOR:</p> <p>25 Q. Ms Harper-Avilla, hello again</p>	<p style="text-align: right;">Page 221</p> <p>1 the whole presentation at this point, so no.</p> <p>2 BY MR. O'CONNOR:</p> <p>3 Q. Do you have any personal knowledge 4 about the statements made in this presentation?</p> <p>5 MR. CHANDLER: Object to form.</p> <p>6 THE WITNESS: I have not reviewed 7 the entire presentation so I cannot speak to 8 that.</p> <p>9 BY MR. O'CONNOR:</p> <p>10 Q. Fair to say, you were not involved 11 in making any of the statements in this 12 presentation, correct, because it was delivered 13 in 2003?</p> <p>14 A. So I do not know if these are 15 statements that DEA has continued to use since 16 that time, so at the time that this 17 presentation was made, I am not aware of those 18 statements. I have not reviewed the entire 19 presentation.</p> <p>20 MR. O'CONNOR: I have no further 21 questions at the moment, but we do reserve the 22 right to leave this deposition open pending the 23 production of the letters from DEA and we are 24 happy to discuss that more offline.</p> <p>25 MR. CHANDLER: Okay.</p>

<p style="text-align: right;">Page 222</p> <p>1 MR. O'CONNOR: Thank you for your 2 time.</p> <p>3 THE VIDEOGRAPHER: Does anyone else 4 have any questions? We are off the record at 5 5:26 p.m., and this concludes today's testimony 6 given by DEA and appearing on their behalf was 7 Stacy Harper-Avilla.</p> <p>8 The total number of media units used 9 was six and will be retained by Veritext Legal 10 Solutions.</p> <p>11 (Whereupon, the proceeding was 12 concluded at 5:26 p.m.)</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 224</p> <p>1 Veritext Legal Solutions 2 1100 Superior Ave 3 Suite 1820 4 Cleveland, Ohio 44114 5 Phone: 216-523-1313</p> <p>6 April 16, 2019</p> <p>7 To: Robert Chandler</p> <p>8 Case Name: In Re: National Prescription Opiate Litigation v 9 Veritext Reference Number: 3282688</p> <p>10 Witness: Stacy Harper-Avilla Deposition Date: 4/11/2019</p> <p>11 Dear Sir/Madam:</p> <p>12 Enclosed please find a deposition transcript. Please have the witness 13 review the transcript and note any changes or corrections on the 14 included errata sheet, indicating the page, line number, change, and 15 the reason for the change. Have the witness' signature notarized and 16 forward the completed page(s) back to us at the Production address 17 shown 18 above, or email to production-midwest@veritext.com</p> <p>19 If the errata is not returned within thirty days of your receipt of 20 this letter, the reading and signing will be deemed waived</p> <p>21 Sincerely, 22 Production Department</p> <p>23</p> <p>24 NO NOTARY REQUIRED IN CA</p>
<p style="text-align: right;">Page 223</p> <p>1 CERTIFICATE OF NOTARY PUBLIC</p> <p>2 I, Bonnie L. Russo, the officer before 3 whom the foregoing deposition was taken, do 4 hereby certify that the witness whose testimony 5 appears in the foregoing deposition was duly 6 sworn by me; that the testimony of said witness 7 was taken by me in shorthand and thereafter 8 reduced to computerized transcription under my 9 direction; that said deposition is a true 10 record of the testimony given by said witness; 11 that I am neither counsel for, related to, nor 12 employed by any of the parties to the action in 13 which this deposition was taken; and further, 14 that I am not a relative or employee of any 15 attorney or counsel employed by the parties hereto, nor financially or otherwise interested 16 in the outcome of the action.</p> <p>17</p> <p>18</p> <p>19 <i>Bonnie L Russo</i></p> <p>20 Notary Public in and for 21 the District of Columbia</p> <p>22</p> <p>23 My Commission expires: June 30, 2020</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 225</p> <p>1 DEPOSITION REVIEW 2 CERTIFICATION OF WITNESS</p> <p>3 ASSIGNMENT REFERENCE NO: 3282688</p> <p>4 CASE NAME: In Re: National Prescription Opiate Litigation v 5 DATE OF DEPOSITION: 4/11/2019</p> <p>6 WITNESS' NAME: Stacy Harper-Avilla</p> <p>7 In accordance with the Rules of Civil 8 Procedure, I have read the entire transcript of 9 my testimony or it has been read to me 10 I have made no changes to the testimony 11 as transcribed by the court reporter</p> <p>12</p> <p>13 They have read the transcript;</p> <p>14 They signed the foregoing Sworn 15 Statement; and 16 Their execution of this Statement is of 17 their free act and deed</p> <p>18 I have affixed my name and official seal</p> <p>19 this _____ day of _____, 20____</p> <p>20</p> <p>21 Notary Public</p> <p>22</p> <p>23 Commission Expiration Date</p> <p>24</p> <p>25</p>

<p>1 DEPOSITION REVIEW CERTIFICATION OF WITNESS</p> <p>2 ASSIGNMENT REFERENCE NO: 3282688</p> <p>3 CASE NAME: In Re: National Prescription Opiate Litigation v DATE OF DEPOSITION: 4/11/2019</p> <p>4 WITNESS' NAME: Stacy Harper-Avilla</p> <p>5 In accordance with the Rules of Civil Procedure, I have read the entire transcript of 6 my testimony or it has been read to me</p> <p>7 I have listed my changes on the attached Errata Sheet, listing page and line numbers as 8 well as the reason(s) for the change(s)</p> <p>9 I request that these changes be entered as part of the record of my testimony</p> <p>10 I have executed the Errata Sheet, as well 11 as this Certificate, and request and authorize that both be appended to the transcript of my 12 testimony and be incorporated therein</p> <p>13 _____ Date Stacy Harper-Avilla</p> <p>14 Sworn to and subscribed before me, a 15 Notary Public in and for the State and County, the referenced witness did personally appear 16 and acknowledge that:</p> <p>17 They have read the transcript; They have listed all of their corrections 18 in the appended Errata Sheet; They signed the foregoing Sworn 19 Statement; and Their execution of this Statement is of 20 their free act and deed</p> <p>21 I have affixed my name and official seal 22 this _____ day of _____, 20_____ 23 _____ Notary Public</p> <p>24</p> <p>25 Commission Expiration Date</p>	<p>Page 226</p>
<p>1 ERRATA SHEET</p> <p>2 VERITEXT LEGAL SOLUTIONS MIDWEST</p> <p>3 ASSIGNMENT NO: 3282688</p> <p>4 PAGE/LINE(S) / CHANGE /REASON 5 _____ 6 _____ 7 _____ 8 _____ 9 _____ 10 _____ 11 _____ 12 _____ 13 _____ 14 _____ 15 _____ 16 _____ 17 _____ 18 _____ 19 _____</p> <p>20 Date Stacy Harper-Avilla 21 SUBSCRIBED AND SWORN TO BEFORE ME THIS _____ 22 DAY OF _____, 20_____. 23 _____ Notary Public</p> <p>24</p> <p>25 Commission Expiration Date</p>	<p>Page 227</p>

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES

ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF SEPTEMBER 1, 2016. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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